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Attorneys for Plaintiff
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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

VNUS MEDICAL TECHNOLOGIES, INC., Plaintiff, v. BIOLITEC, INC., DORNIER MEDTECH AMERICA, INC., and NEW STAR LASERS, INC. d/b/a COOLTOUCH, INC. Defendants.	CASE NO. **COMPLAINT FOR PATENT INFRINGEMENT** **DEMAND FOR JURY TRIAL**

Plaintiff VNUS Medical Technologies, Inc. ("VNUS") alleges for its complaint against Defendants biolitec, Inc. ("Biolitec"), Dornier MedTech America, Inc. ("Dornier") and New Star Lasers, Inc. d/b/a CoolTouch, Inc. ("CoolTouch") (collectively "Defendants") as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

3. This Court has personal jurisdiction because, on information and belief, Defendants do business and have committed infringing activities in the state of California, including within this district.

4. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

INTRADISTRICT ASSIGNMENT

5. This case is exempt from intradistrict assignment pursuant to Civil L. R. 3-2(c) because it is a patent infringement action.

PARTIES

6. VNUS is a Delaware corporation having its principal executive offices at 5799 Fontanoso Way, San Jose, CA 95138.

7. On information and belief, Biolitec is a New Jersey corporation with a place of business at 515 Shaker Road, East Longmeadow, MA 01028.

8. On information and belief, Dornier is a Georgia corporation with a place of business at 1155 Roberts Blvd., Kennesaw, GA 30144. The name and address of Dornier's registered agent in California is: Lawyers Incorporating Service, 2730 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833.

9. On information and belief, CoolTouch is a California corporation with a place of business at 9085 Foothills Blvd., Roseville, CA 95747.

THE PATENTS

10. VNUS owns all right, title and interest in U.S. Patent Nos. 6,752,803 entitled "METHOD AND APPARATUS FOR APPLYING ENERGY TO BIOLOGICAL TISSUE INCLUDING THE USE OF TUMESCENT TISSUE COMPRESSION" (the "'803 patent"); 6,769,433 entitled "EXPANDABLE VEIN LIGATOR CATHETER HAVING MULTIPLE ELECTRODE LEADS, AND METHOD" (the "'433 patent"); and 6,258,084 entitled "METHOD FOR APPLYING ENERGY TO BIOLOGICAL TISSUE INCLUDING THE USE OF TUMESCENT TISSUE COMPRESSION" (the "'084 patent"). Copies of these patents are attached hereto as Exhibits 1-3.

THE INFRINGEMENT

11. Biolitec has directly and/or indirectly infringed (including contributory and/or inducement of infringement) the claims of the '803, '433 and '084 patents by making, using,

selling, offering to sell and/or instructing users how to use products for endovenous laser treatment, including the Biolitec "ELVeS – Endo Laser Vein System" and "ELVeS PL." Biolitec continues to directly and/or indirectly infringe (including contributory and/or inducement of infringement) the '803, '433 and '084 patents.

12. Dornier has directly and/or indirectly infringed (including contributory and/or inducement of infringement) the claims of the '803, '433 and '084 patents by making, using, selling, offering to sell and/or instructing users how to use products for endovenous laser treatment, including laser fibers, the Dornier D940 laser system, and the Medilas D Family Lasers, Fibertom, SkinPulse and SkinPulse S lasers. Dornier continues to directly and/or indirectly infringe (including contributory and/or inducement of infringement) the '803, '433 and '084 patents.

13. CoolTouch has directly and/or indirectly infringed (including contributory and/or inducement of infringement) the claims of the '803, '433 and '084 patents by making, using, selling, offering to sell and/or instructing users how to use products for endovenous laser treatment, including the "CoolTouch CTEV System," laser fibers, pull-back devices and lasers. CoolTouch continues to directly and/or indirectly infringe (including contributory and/or inducement of infringement) the '803, '433 and '084 patents.

14. VNUS has been damaged by Defendants' infringing activities and will be irreparably injured by their continued infringement unless Defendants are enjoined by this Court.

15. On information and belief, Defendants' infringement of the '803, '433 and '084 patents has been and is willful and will continue unless enjoined by this Court.

RELIEF REQUESTED

WHEREFORE, VNUS prays that judgment be entered in its favor, that:

(a) Defendants have infringed and are infringing the '803, '433 and '084 patents;

(b) Defendants' infringement of the '803, '433 and '084 patents has been and is willful;

(c) Defendants be preliminarily and permanently enjoined, along with their officers, directors, agents, employees, attorneys, parents, subsidiaries, and all others acting by or through Defendants, controlled by Defendants, or acting in concert or participating with Defendants, from further infringing the '803, '433 and '084 patents;

(d) Defendants account to VNUS for damages adequate to compensate for Defendants' infringement of the '803, '433 and '084 patents and that such damages be awarded to VNUS, including prejudgment and postjudgment interest;

(e) VNUS's damages be trebled as a result of Defendants' willful infringement of the '803, '433 and '084 patents;

(f) This case be adjudged an exceptional case and that the Court award VNUS its costs, expenses and attorneys' fees incurred in bringing and prosecuting this action; and

(g) VNUS be awarded such further and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

VNUS hereby demands a trial by jury on its claims for patent infringement.

Dated: June 27, 2008

Respectfully Submitted,

ATTORNEYS FOR PLAINTIFF
VNUS MEDICAL TECHNOLOGIES, INC.

By: _____

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EXHIBIT 1

US006752803B2

(12) **United States Patent**
Goldman et al.

(10) **Patent No.: US 6,752,803 B2**
(45) **Date of Patent: *Jun. 22, 2004**

(54) **METHOD AND APPARATUS FOR APPLYING ENERGY TO BIOLOGICAL TISSUE INCLUDING THE USE OF TUMESCENT TISSUE COMPRESSION**

(75) Inventors: **Mitchel P. Goldman**, La Jolla, CA (US); **Robert A. Weiss**, Baltimore, MD (US); **Arthur W. Zikorus**, San Jose, CA (US); **James G. Chandler**, Boulder, CO (US)

(73) Assignee: **VNUS Medical Technologies, Inc.**, San Jose, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/899,885**

(22) Filed: **Jul. 6, 2001**

(65) **Prior Publication Data**

US 2001/0041888 A1 Nov. 15, 2001

Related U.S. Application Data

(63) Continuation of application No. 09/267,127, filed on Mar. 10, 1999, now Pat. No. 6,258,084, which is a continuation-in-part of application No. 09/138,472, filed on Aug. 21, 1998, now Pat. No. 6,179,832, which is a continuation-in-part of application No. 08/927,251, filed on Sep. 11, 1997, now Pat. No. 6,200,312.

(51) **Int. Cl.**[7] **A61B 18/04**
(52) **U.S. Cl.** **606/32**; 128/898; 606/41
(58) **Field of Search** 128/898; 606/27–29, 606/31, 32, 34, 41, 42; 607/96, 98, 100–102, 104–106

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Primary Examiner—Rosiland Rollins
(74) *Attorney, Agent, or Firm*—Fulwider Patton Lee & Utecht, LLP

(57) **ABSTRACT**

An electrode catheter is introduced into a hollow anatomical structure, such as a vein, and is positioned at a treatment site within the structure. Tumescent fluid is injected into the tissue surrounding the treatment site to produce tumescence of the surrounding tissue which then compresses the vein. The solution may include an anesthetic, and may further include a vasoconstrictive drug that shrinks blood vessels. The tumescent swelling in the surrounding tissue causes the hollow anatomical structure to become compressed, thereby exsanguinating the treatment site. Energy is applied by an electrode catheter in apposition with the vein wall to create a heating effect. The heating effect causes the hollow anatomical structure to become molded and durably assume the compressed dimensions caused by the tumescent technique. The electrode catheter can be moved within the structure so as to apply energy to a large section of the hollow anatomic structure. In a further aspect, the location of the electrodes is determined by impedance monitoring. Also, temperature sensors at the treatment site are averaged to determine the site temperature.

20 Claims, 6 Drawing Sheets

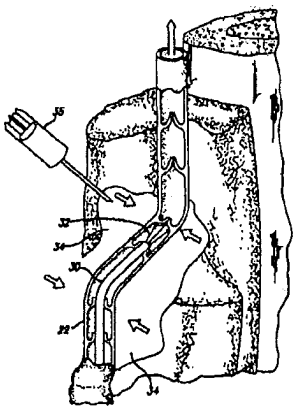

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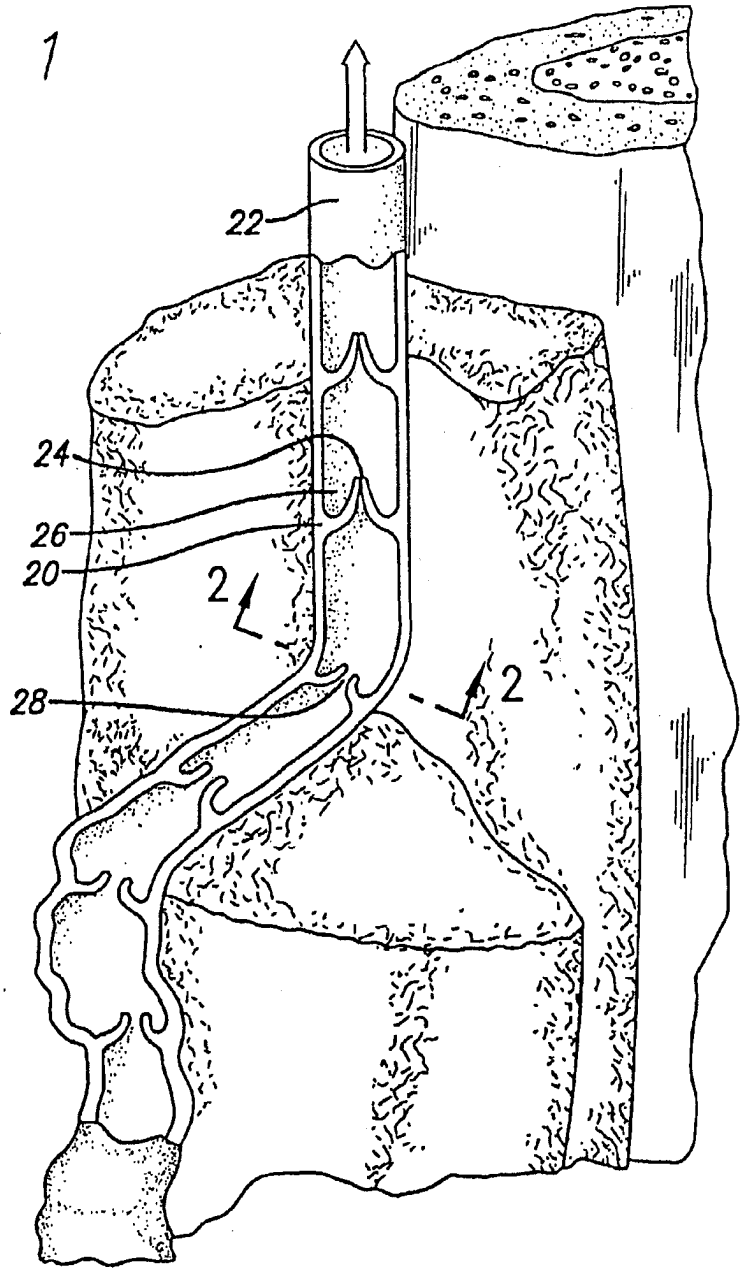
FIG. 1



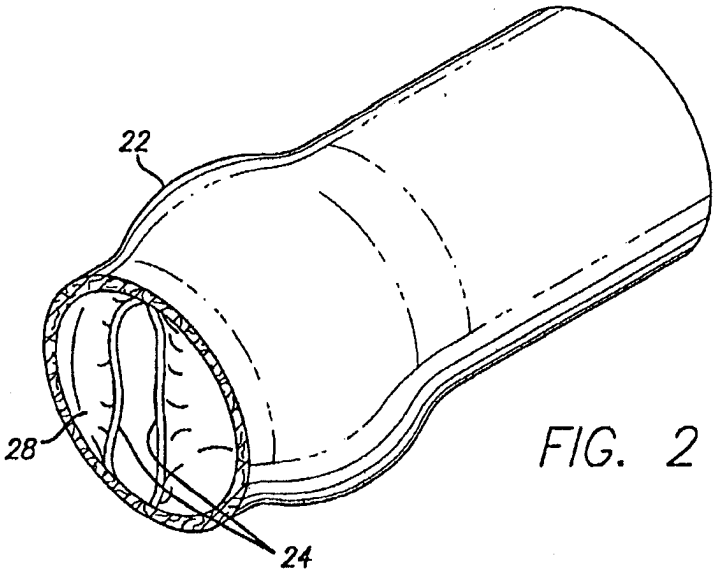


FIG. 2

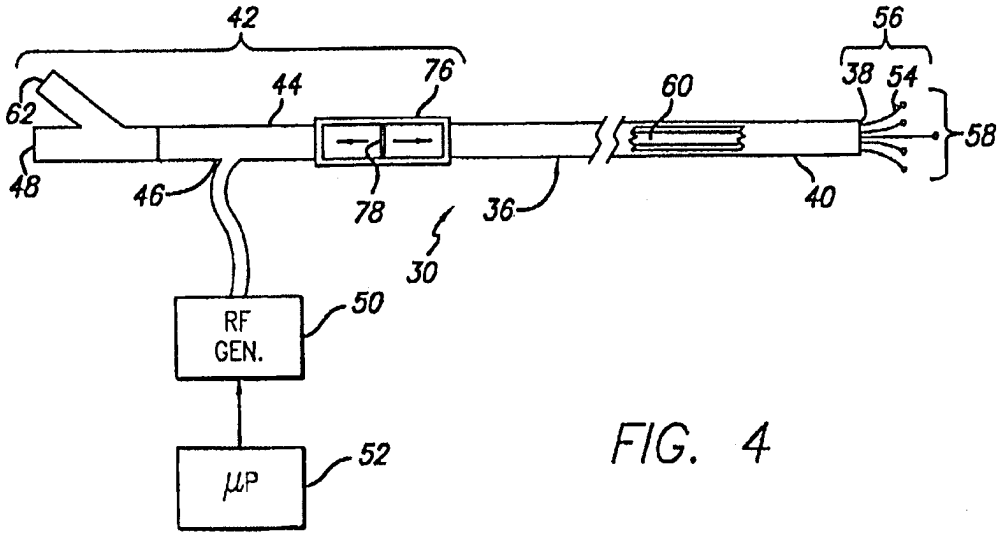
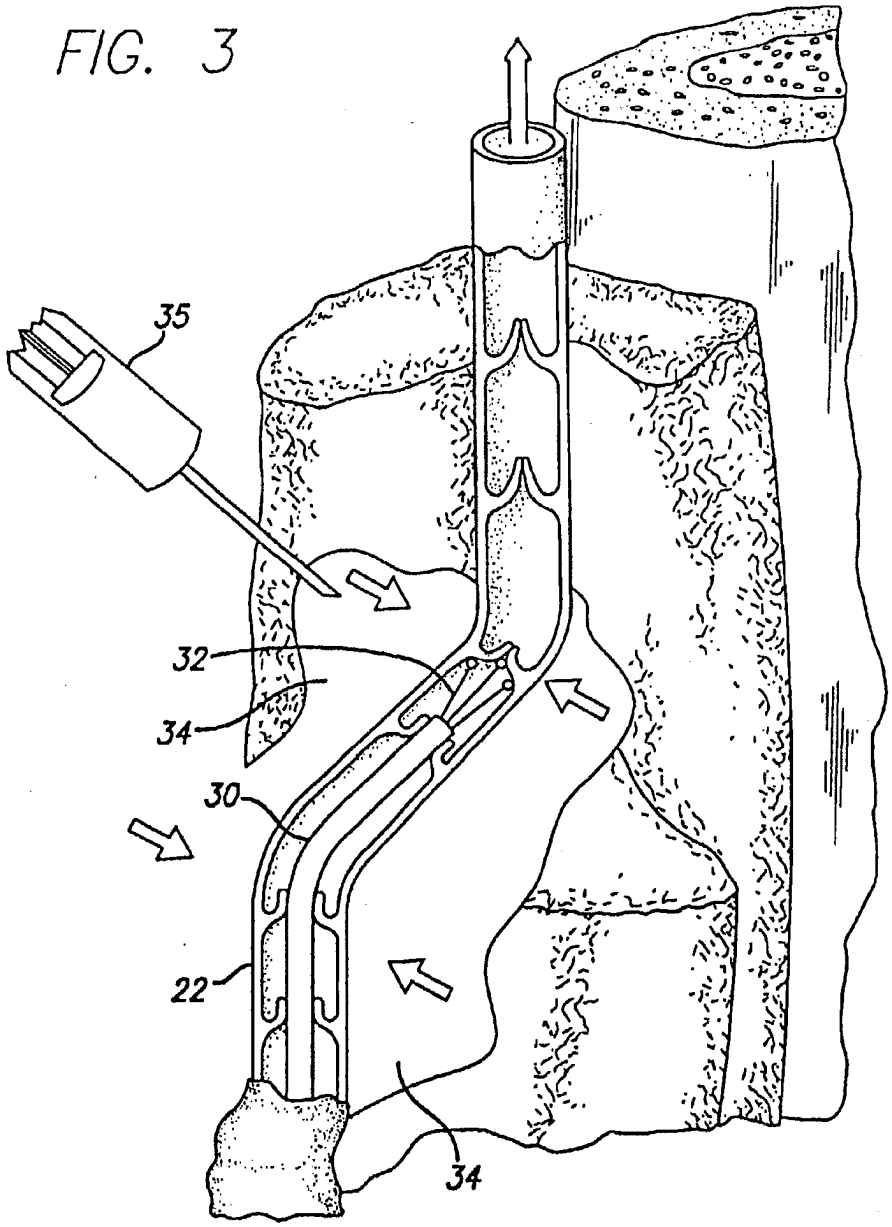


FIG. 4

FIG. 3



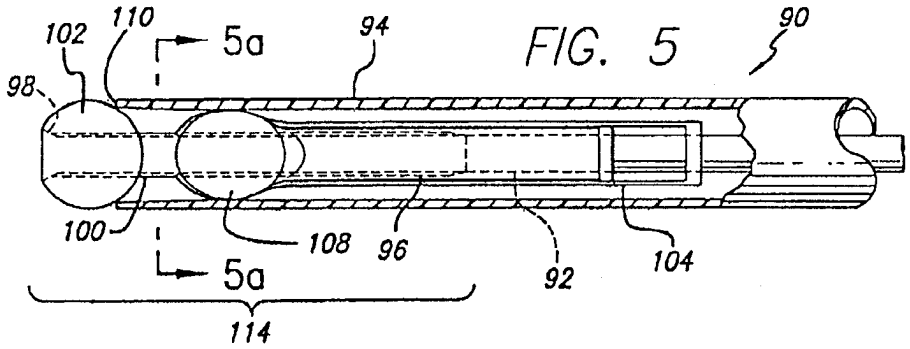


FIG. 5

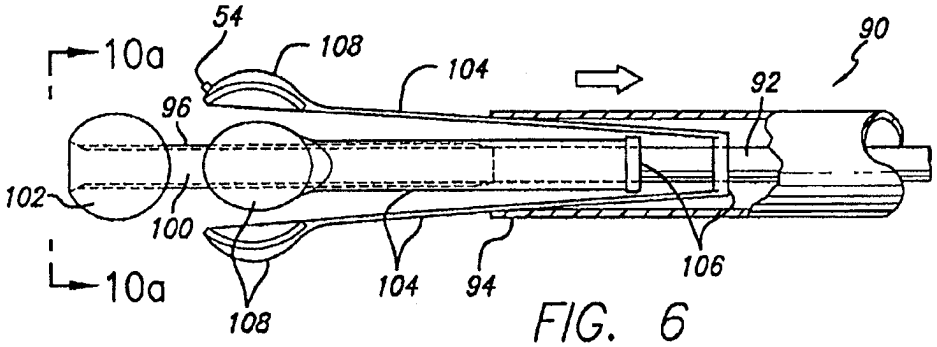


FIG. 6

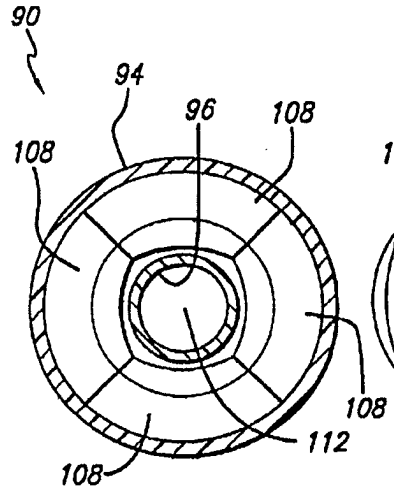


FIG. 5a

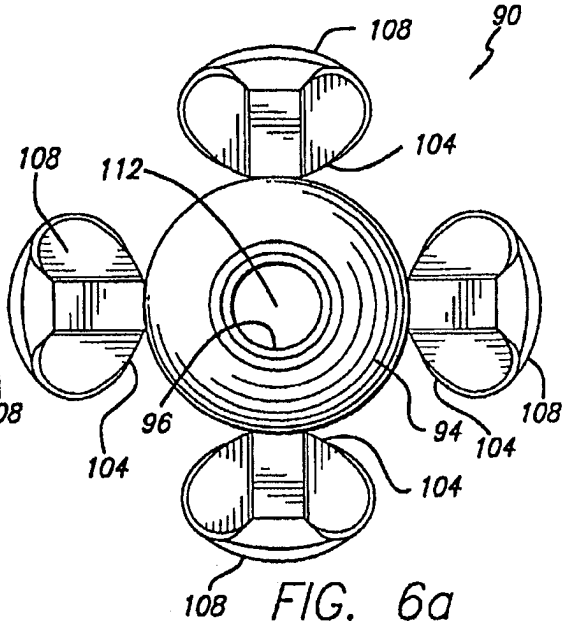


FIG. 6a

FIG. 7

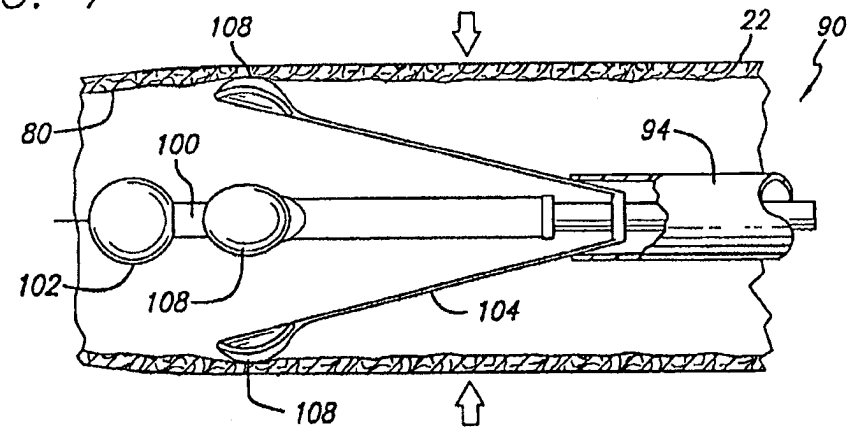


FIG. 8

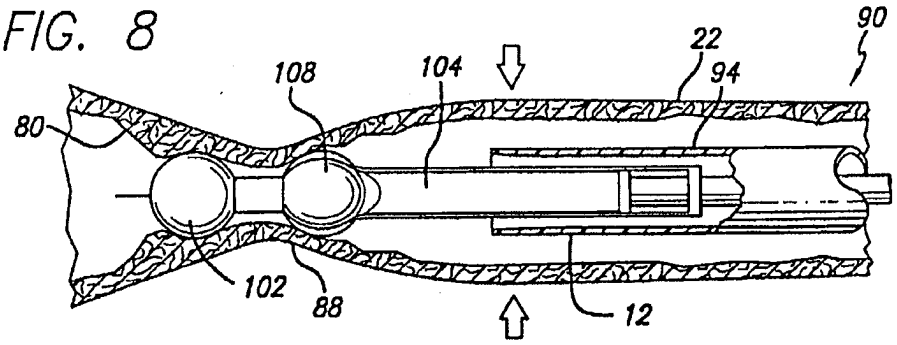
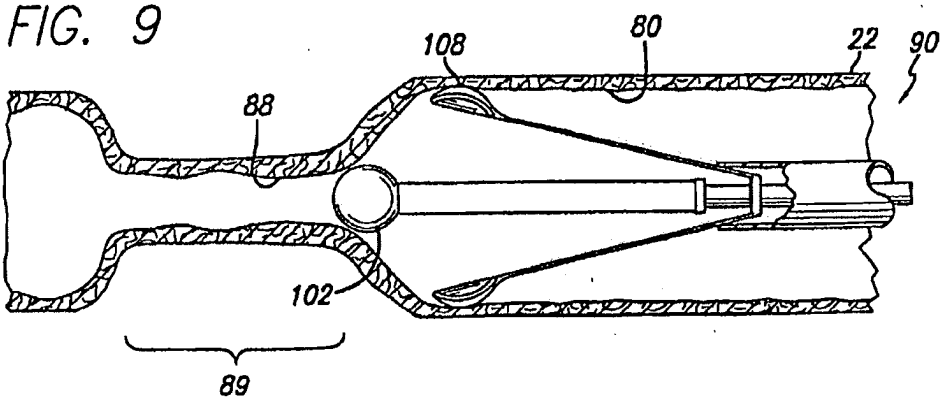


FIG. 9



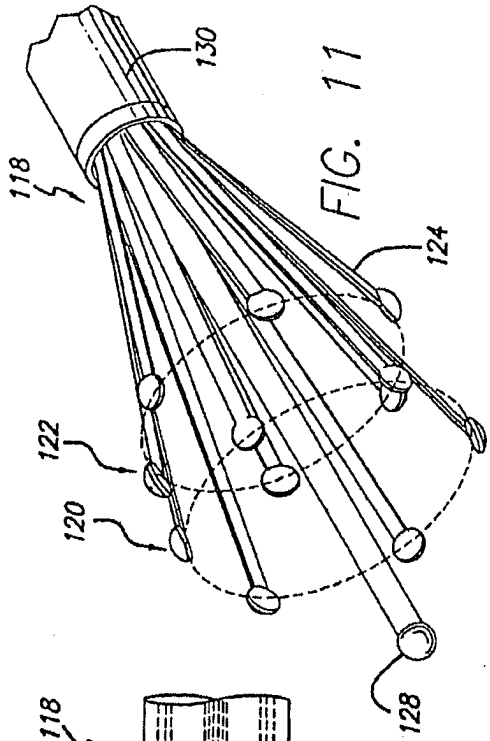


FIG. 11

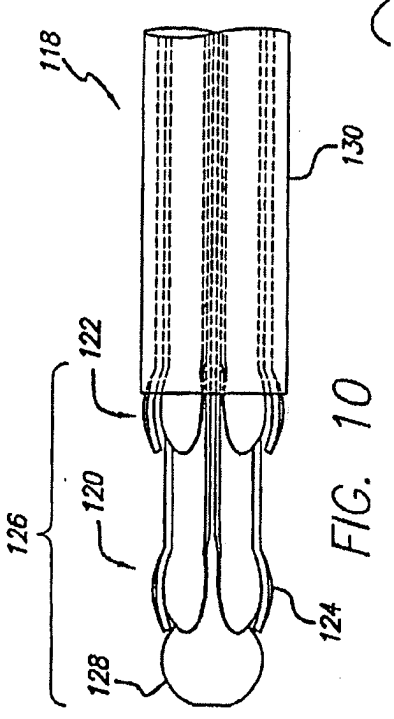


FIG. 10

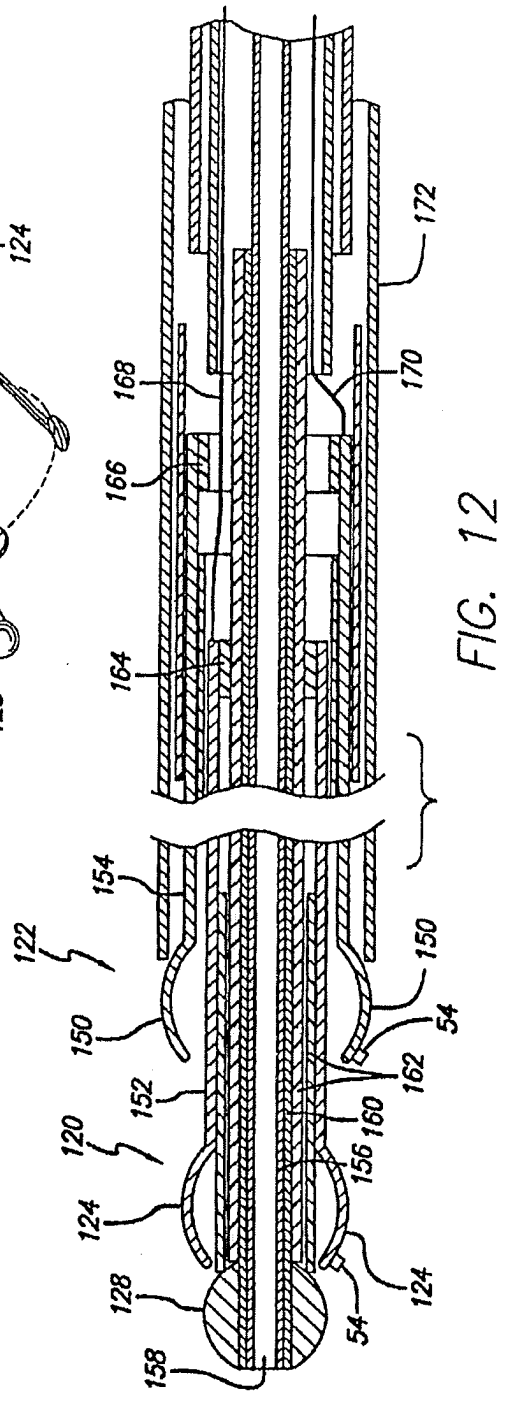


FIG. 12

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METHOD AND APPARATUS FOR APPLYING ENERGY TO BIOLOGICAL TISSUE INCLUDING THE USE OF TUMESCENT TISSUE COMPRESSION

This application is a continuation of application Ser. No. 09/267,127 filed Mar. 10, 1999 now U.S. Pat. No. 6,258,084, which is a continuation-in-part of application Ser. No. 09/138,472, filed Aug. 21, 1998, now U.S. Pat. No. 6,179,832 which is a continuation-in-part of application Ser. No. 08/927,251 filed on Sep. 11, 1997, now U.S. Pat. No. 6,200,312.

BACKGROUND

The invention relates generally to a method and apparatus for applying energy to shrink a hollow anatomical structure, such as a fallopian tube or a vein, including but not limited to, superficial and perforator veins, hemorrhoids, and esophageal varices. In some particular aspects, the invention relates to a method for compressing an anatomical structure prior to the application of energy and apparatus including an electrode device having multiple leads for applying energy to the compressed structure to cause it to durably assume its compressed form.

The human venous system of the lower limbs consists essentially of the superficial venous system and the deep venous system with perforating veins connecting the two systems. The superficial system includes the long or great saphenous vein and the short saphenous vein. The deep venous system includes the anterior and posterior tibial veins which unite to form the popliteal vein, which in turn becomes the femoral vein when joined by the short saphenous vein.

The venous system contains numerous one-way valves for directing blood flow back to the heart such as those valves **20** located in the vein **22** shown in FIG. **1**. The arrow leading out the top of the vein represents the antegrade flow of blood back to the heart. Venous valves are usually bicuspid valves, with each cusp **24** forming a sack or reservoir **26** for blood which, under retrograde blood pressure, forces the free surfaces of the cusps together to prevent retrograde flow of the blood and allows only antegrade blood flow to the heart. Competent venous valves prevent retrograde flow as blood is pushed forward through the vein lumen and back to the heart. When an incompetent valve **28** is in the flow path, the valve is unable to close because the cusps do not form a proper seal and retrograde flow of the blood cannot be stopped. When a venous valve fails, increased strain and pressure occur within the lower venous sections and overlying tissues, sometimes leading to additional valvular failure. Incompetent valves may result from the stretching of dilated veins. As the valves fail, increased pressure is imposed on the lower veins and the lower valves of the vein, which in turn exacerbates the failure of these lower valves. A cross-sectional perspective view of a dilated vein with an incompetent valve **28** taken along lines **2**—**2** of FIG. **1** is illustrated in FIG. **2**. The valve cusps **24** can experience some separation at the commissure due to the thinning and stretching of the vein wall at the cusps. Two venous conditions which often result from valve failure are varicose veins and more symptomatic chronic venous insufficiency.

The varicose vein condition includes dilation and tortuosity of the superficial veins of the lower limbs, resulting in unsightly discoloration, pain, swelling, and possibly ulceration. Varicose veins often involve incompetence of one or more venous valves, which allow reflux of blood within the superficial system. This can also worsen deep venous reflux and perforator reflux. Current treatments of vein insufficiency include surgical procedures such as vein stripping, ligation, and occasionally, vein-segment transplant.

Chronic venous insufficiency involves an aggravated condition of varicose veins which may be caused by degenerative weakness in the vein valve segment, or by hydrodynamic forces acting on the tissues of the body, such as the legs, ankles, and feet. As the valves in the veins fail, the hydrostatic pressure increases on the next venous valves down, causing those veins to dilate. As this continues, more venous valves will eventually fail. As they fail, the effective height of the column of blood above the feet and ankles grows, and the weight and hydrostatic pressure exerted on the tissues of the ankle and foot increases. When the weight of that column reaches a critical point as a result of the valve failures, ulcerations of the ankle begin to form, which start deep and eventually come to the surface. These ulcerations do not heal easily because of poor venous circulation due to valvular incompetence in the deep venous system and other vein systems.

Other related venous conditions include dilated hemorrhoids and esophageal varices. Pressure and dilation of the hemorrhoid venous plexus may cause internal hemorrhoids to dilate and/or prolapse and be forced through the anal opening. If a hemorrhoid remains prolapsed, considerable discomfort, including itching and bleeding, may result. The venous return from these prolapsed hemorrhoids becomes obstructed by the anal sphincters, which gives rise to a strangulated hemorrhoid. Thromboses result where the blood within the prolapsed vein becomes clotted. This extremely painful condition can cause edema and inflammation.

Varicose veins called esophageal varices can form in the venous system with submucosa of the lower esophagus, and bleeding can occur from the dilated veins. Bleeding or hemorrhaging may result from esophageal varices, which can be difficult to stop and, if untreated, could develop into a life threatening condition. Such varices erode easily, and lead to a massive gastrointestinal hemorrhage.

Ligation of a fallopian tube (tubal ligation) for sterilization or other purposes is typically performed by laparoscopy. A doctor severs the fallopian tube or tubes and ties the ends. External cauterization or clamps may also be used. General or regional anesthetic must be used. All of the above are performed from outside the fallopian tube.

Hemorrhoids and esophageal varices may be alleviated by intra-luminal ligation. As used herein, "ligation" or "intra-luminal ligation" comprises the occlusion, collapse, or closure of a lumen or hollow anatomical structure by the application of energy from within the lumen or structure. As used herein, "ligation" or "intra-luminal ligation" includes electro-ligation. In the case of fallopian tube ligation, it would be desirable to perform the ligation from within the fallopian tube itself (intra-fallopian tube) to avoid the trauma associated with external methods.

Ligation involves the cauterization or coagulation of a lumen using energy, such as that applied through an electrode device. An electrode device is introduced into the lumen and positioned so that it contacts the lumen wall. Once properly positioned, RF energy is applied to the wall by the electrode device thereby causing the wall to shrink in cross-sectional diameter. In the case of a vein, a reduction in cross-sectional diameter of the vein, as for example from 5 mm (0.2 in) to 1 mm (0.04 in), significantly reduces the flow of blood through a lumen and results in an effective occlu-

sion. Although not required for effective occlusion or ligation, the vein wall may completely collapse thereby resulting in a full-lumen obstruction that blocks the flow of blood through the vein. Likewise, a fallopian tube may collapse sufficiently to effect a sterilization of the patient.

One apparatus for performing ligation includes a tubular shaft having an electrode device attached at the distal tip. Running through the shaft, from the distal end to the proximal end, are electrical leads. At the proximal end of the shaft, the leads terminate at an electrical connector, while at the distal end of the shaft the leads are connected to the electrode device. The electrical connector provides the interface between the leads and a power source, typically an RF generator. The RF generator operates under the guidance of a control device, usually a microprocessor.

The ligation apparatus may be operated in either a monopolar or bipolar configuration. In the monopolar configuration, the electrode device consists of an electrode that is either positively or negatively charged. A return path for the current passing through the electrode is provided externally from the body, as for example by placing the patient in physical contact with a large low-impedance pad. The current flows between the ligation device and low impedance pad through the patient. In a bipolar configuration, the electrode device consists of a pair of electrodes having different potentials (such as a pair of oppositely-charged electrodes) of approximately equal size, separated from each other, such as by a dielectric material or by a spatial relationship. Accordingly, in the bipolar mode, the return path for current is provided by an electrode or electrodes of the electrode device itself. The current flows from one electrode, through the tissue, and returns by way of the another electrode.

To protect against tissue damage, i.e., charring, due to cauterization caused by overheating, a temperature sensing device is typically attached to the electrode device, although it may be located elsewhere. The temperature sensing device may be a thermocouple that monitors the temperature of the venous tissue. The thermocouple interfaces with the RF generator and the controller through the shaft and provides electrical signals to the controller which monitors the temperature and adjusts the energy applied to the tissue through the electrode device accordingly.

The overall effectiveness of a ligation apparatus is largely dependent on the electrode device contained within the apparatus. Monopolar and bipolar electrode devices that comprise solid devices having a fixed shape and size can limit the effectiveness of the ligating apparatus for several reasons. Firstly, a fixed-size electrode device typically contacts the vein wall at only one point or a limited arc on the circumference or inner diameter of the vein wall. As a result, the application of RF energy is highly concentrated within the contacting venous tissue, while the flow of RF current through the remainder of the venous tissue is disproportionately weak. Accordingly, the regions of the vein wall near the area of contact collapse at a faster rate than other regions of the vein wall, resulting in non-uniform shrinkage of the vein lumen. Furthermore, the overall strength of the occlusion may be inadequate and the lumen may eventually reopen. To avoid an inadequate occlusion, RF energy must be applied for an extended period of time so that the current flows through the tissue, including through the tissue not in contact with the electrode, generating thermal energy and causing the tissue to shrink sufficiently. Extended applications of energy have a greater possibility of increasing the temperature of the blood to an unacceptable level and may result in a significant amount of heat-induced coagulum forming on the electrode and in the vein which is not desirable. Furthermore, it is possible for the undesirable coagulum to form when utilizing an expandable electrode as well. This problem can be prevented by exsanguination of the vein prior to the treatment, as well as through the use of temperature-regulated power delivery. As used herein, "exsanguination" comprises the removal of all or some significant portion of blood in a particular area.

Secondly, the effectiveness of a ligating apparatus having a fixed-size electrode device is limited to certain sized veins. An attempt to ligate a vein having a diameter that is substantially greater than the fixed-size electrode device can result in not only non-uniform heating of the vein wall as just described, but also insufficient shrinkage of the vein diameter. The greater the diameter of the vein relative to the diameter of the electrode device, the weaker the energy applied to the vein wall at points distant from the point of electrode contact. Also, larger diameter veins must shrink a larger percentage for effective occlusion to occur. Accordingly, the vein wall is likely to not completely collapse prior to the venous tissue becoming over-cauterized at the point of electrode contact. While coagulation as such may initially occlude the vein, such occlusion may only be temporary in that the coagulated blood may eventually dissolve recanalizing the vein. One solution for this inadequacy is an apparatus having interchangeable electrode devices with various diameters. Another solution is to have a set of catheters having different sizes so that one with the correct size for the diameter of the target vein will be at hand when needed. Such solutions, however, are both economically inefficient and can be tedious to use. It is desirable to use a single catheter device that is usable with a large range of sizes of lumina.

A technique of reducing the diameter of the lumen of a vein at least close to the final desired diameter before applying energy to the vein has been found to aid in the efficiency of these types of procedures. The pre-reduction in vein diameter assists in pre-shaping the vein to be molded into a ligated state. The compression also exsanguinates the vein and forces blood away from the treatment site, thus preventing coagulation. One valuable technique employed is that of compressing the vein contained within a limb by applying external hydraulic pressure, via a pressure tourniquet, to the limb. Unfortunately there are some areas of the body to which a pressure tourniquet cannot be applied, such as the sapheno-femoral junction, which is above the thigh proximate the groin area. Furthermore, there are sites where a pressure tourniquet may be ineffective such as: the popliteal junction and other areas around the knee; and the ankle area (typically the posterior arch vein and some of the lower cockett perforators).

There exists a technique referred to as tumescent anesthesia that has been used in connection with liposuction procedures. The word "tumescent" means swollen or firm. This technique is accomplished by subcutaneously delivering into target fatty tissue a large volume of saline solution containing diluted Lidocaine and Epinephrine (adrenaline), a vasoconstrictive drug. The injected area then becomes locally anesthetized, and the adrenaline temporarily constricts the capillaries and other blood vessels. The tumescence-inducing fluid, or "tumescent fluid" is injected under pressure which causes the target fatty tissue to become swollen and firm. The tumescent fluid is typically pumped into the pocket of fat in order to numb the area, loosen the fat, and constrict the blood vessels to minimize bleeding or bruising in a liposuction procedure. The anesthetic and other agents in the tumescent solution should be allowed sufficient

time to diffuse and take full effect throughout the target tissue. After surgery, patients may leave without assistance, and often return to their regular routine within several days. With the tumescent technique, postoperative discomfort is significantly reduced. The local anesthesia often remains in the treated tissue for 16 hours after surgery. Employing a technique of utilizing tumescent anesthesia in conjunction with ligation or radial lumen shrinkage less than ligation may provide benefits.

Although described above in terms of a vein, the concepts are generally applicable to other hollow anatomical structures in the body as well. The above description has been generally confined to veins in consideration of avoiding unnecessary repetition.

Hence those skilled in the art have recognized a need for an improved method and apparatus that can be used on areas of the body to shrink and ligate hollow anatomical structures. A need has also been recognized for an improved method and apparatus to pre-compress and exsanguinate a hollow anatomical structure while providing anesthetic and insulation benefits during the radial shrinkage of the hollow anatomical structure. The invention fulfills these needs and others.

SUMMARY OF THE INVENTION

The present invention is directed to a method and apparatus for applying energy to a hollow anatomical structure such as a vein, to shrink the structure. In a more detailed aspect, the invention is directed to pre-compressing and exsanguinating a hollow anatomical structure while providing anesthetic and insulation benefits during a procedure of shrinking the hollow anatomical structure.

In another aspect of the present invention, a method comprises providing fluid to tissue surrounding a hollow anatomical structure to induce tumescence of the tissue and consequent compression of the hollow anatomical structure during a procedure of applying energy to the hollow anatomical structure from within the structure. In a more detailed aspect, the method comprises introducing into the hollow anatomical structure a catheter having a working end and at least one electrode at the working end; placing the electrode into contact with the inner wall of the pre-compressed hollow anatomical structure and applying energy to the hollow anatomical structure at the treatment site via the electrode until the hollow anatomical structure durably assumes dimensions less than or equal to the pre-compressed dimensions caused by the injection of the solution into the tissue.

In another aspect in accordance with the invention, tumescent fluid is injected in the tissue surrounding the hollow anatomical structure along a selected length of the hollow anatomical structure. The electrode is then moved along a site within the selected length while continuously applying energy to result in a lengthy occlusion. In another approach, after an initial application of energy to one site internal to the hollow anatomical structure within the selected length, the electrode is moved down a given length of the hollow anatomical structure and energy is applied at that adjacent site. For the site where energy is applied, the hollow anatomical structure durably assumes dimensions less than or equal to the pre-compressed dimensions caused by the injection of the solution into the tissue.

In a more detailed aspect, tumescent anesthesia fluid is injected or otherwise provided to tissue contiguous with a vein to compress the vein to about a desired final diameter. A catheter having an energy application device, such as expandable electrodes, is introduced internal to the vein at a site within the compressed portion of the vein and energy is applied to the internal vein wall by the application device. Sufficient energy is applied to cause the vein to durably assume the compressed diameter such that when the effects of the tumescent anesthesia fluid are dissipated, the vein retains the compressed diameter.

Alternate means to prevent coagulum formation include fluid displacement of blood at the treatment site, or exsanguination by inducing self-constriction of the vessel. In the latter, self-constriction includes, but is not limited to, intraluminal delivery of a vasoconstrictive drug. Self-constriction also aids in pre-shaping the vein for ligation, as discussed previously. If the fluid delivered to the site is a sclerosant, the ligation effects would be further enhanced.

In further aspects, energy is applied to effectively occlude the treatment site. Further, the energy application device is moved along the treatment site while performing the step of applying energy so as to result in a lengthy occlusion of the treatment site. The treatment site may collapse around the energy application device as it is being moved. In yet further detail, fluid is delivered from within the hollow structure to the treatment site. This fluid may be used to exsanguinate the treatment site. Such fluid may be from the following group: saline; a vasoconstrictive agent; a sclerosing agent; a high impedance fluid; and heparin.

In another aspect, temperatures are sensed at two separate locations on the energy application device, and the temperature signals are averaged to determine the temperature at the site. In further detailed aspects, electrical energy is applied to the inner wall of the treatment site with an electrode, the electrode being in apposition with the inner wall. With the electrode being in apposition with the inner wall, the method further comprises the steps of applying electrical energy with the electrode to effectively occlude the treatment site at the electrode, and moving the electrode along the treatment site while maintaining the electrode in apposition with the vein wall while performing the step of applying energy to effectively occlude the treatment site so as to result in a lengthy effective occlusion of the treatment site. Sufficient energy is applied to collapse the hollow anatomical structure around the energy application device as it is being moved along the treatment site to result in a lengthy effective occlusion of the treatment site.

In yet a further aspect, apposition of the energy application device with the inner wall of the hollow anatomical structure is determined by monitoring the impedance experienced by the energy application device.

These and other aspects and advantages of the present invention will become apparent from the following more detailed description, when taken in conjunction with the accompanying drawings which illustrate, by way of example, embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a cross-sectional view of a vein having competent valves and having a dilated section with incompetent venous valves in a lower limb which are to be treated in accordance with the present invention;

FIG. **2** shows a representative view of a venous section with an incompetent valve from FIG. **1** taken along lines **2**—**2** which is to be treated in accordance with the present invention;

FIG. **3** is a cross-sectional view of the vein of FIG. **1** after the vein has been compressed, although not to full occlusion, by the injection of a tumescent anesthesia fluid in tissue

surrounding the vein showing a catheter including an expandable electrode device prior to the application of energy to the vein;

FIG. **4** is a diagram of an energy application system that may be used in conjunction with the method of the present invention, depicting a partial cutaway view of the first embodiment of the catheter showing both the working end and the connecting end with an RF generator and a microprocessor connected at the connection end;

FIG. **5** is a cross-sectional view of the working end of an embodiment of a catheter in accordance with the invention depicting the electrodes in a fully retracted position;

FIG. **5***a* is an end view of the working end of the embodiment of the catheter taken along line **5***a*—**5***a* of FIG. **5**;

FIG. **6** is a cross-sectional view of the working end of the embodiment of the catheter of FIGS. **5** and **5***a* depicting the electrodes in a fully expanded position;

FIG. **6***a* is an end view of the working end of the embodiment of the catheter taken along line **6***a*—**6***a* of FIG. **6**;

FIG. **7** is a cross-sectional view of a vein after the vein has been compressed, although not to full occlusion, by tumescent anesthesia fluid, the vein containing the catheter of FIG. **5** with the electrodes in apposition with the vein;

FIG. **8** is a cross-sectional view of the compressed vein containing the catheter of FIG. **5** where the vein is being ligated by the application of energy from the electrodes;

FIG. **9** is a partial cross-sectional view of the vein wall of FIG. **8** showing a lengthy effective occlusion made by moving the electrodes along the treatment site of the vein while maintaining the electrodes in apposition and continuing to apply energy to the vein wall.

FIG. **10** is a side view of an embodiment of an electrode catheter having two pluralities of longitudinally-separated expandable electrodes in a retracted condition;

FIG. **11** is a side view of the embodiment of the electrode catheter of FIG. **10** with both pluralities of the electrodes in expanded configurations; and

FIG. **12** is a partial cross-sectional view of the embodiment of an electrode catheter of FIGS. **10** and **11**.

DETAILED DESCRIPTION OF THE EMBODIMENTS

As shown in the exemplary drawings, the invention is directed toward the intravenous treatment of veins using a catheter to deliver at least one electrode to a venous treatment site. As used herein, like reference numerals will designate similar elements in the various embodiments of the present invention to be discussed. In addition, unless otherwise noted, the term "working end" will refer to the direction toward the treatment site in the patient, and the term "connecting end" will refer to the direction away from the treatment site in the patient. The invention will be described in relation to the treatment of the venous system of the lower limbs. It is to be understood, however, that the invention is not limited thereto and may be employed intraluminally to treat veins in other areas of the body such as hemorrhoids, esophageal varices, and venous-drainage-impotence of the penis. Furthermore, although the invention will be described as using RF energy from the electrode, it is to be understood that other forms of energy such as microwaves, ultrasound, direct current, circulating heated fluid, radiant light, and lasers can be used, and that the thermal energy generated from a resistive coil or curie point element may be used as well.

Turning to FIG. **3**, one preferred method of the present invention can be performed using the catheter **30** to deliver an expandable electrode device **32** (partially shown) to a venous treatment site in order to ligate the vein. Instead of compressing the tissue surrounding the treatment site via a pressure tourniquet, a tumescent anesthesia technique can be used to inject a dilute anesthetic and vasoconstrictive solution into the tissue surrounding the vein to be treated. The tumescent solution preferably includes mostly saline solution, with a local anesthetic such as Lidocaine, and a vasoconstrictive drug such as Epinephrine. The tumescent solution causes the surrounding tissue **34** to become swollen which compresses the vein **22**, as indicated by the arrows, close to occlusion (in this case) or to occlusion. Sufficient tumescent solution should be delivered into the tissue surrounding the vein to compress and exsanguinate the vein. Before injecting the tumescent solution, the catheter **30** is placed within the vein at the treatment site, with the expandable electrode device retracted.

The solution is typically infused with a peristaltic pump. However, 60 cc or 100 cc syringes **35** can be used. Another alternative is an IV bag with a pressure cuff. Large volumes are typically delivered into the perivenal area via a large cannula. Sites are typically located 10 cm apart down the leg. Usually there are four or five delivery sites. The external result is a leg that appears inflated. The internal result is compressed veins plus an anesthetized leg. The expandable electrode device is then expanded into apposition with the venous tissue after compression of the vein. Energy such as high frequency RF energy is applied from the expandable electrode device to the venous tissue until the vein durably assumes dimensions less than or equal to the compressed dimensions caused by the injection of the tumescent solution into the tissue.

After completing the procedure for a selected venous section or treatment site, the electrode may be retracted and the catheter moved to another venous section where the ligation process is repeated. Ultrasound guidance can be used to monitor the progress of the procedure.

One preferred embodiment of the catheter for delivering an expandable energy application device or expandable electrode device **56** to the venous treatment site is illustrated in FIG. **4**. The catheter **30** includes an expandable energy application device **56** which in this embodiment, comprises an array of electrodes **58**, an outer sheath **36** having a distal orifice **38** at its working end **40**. The connector end **42** of the outer sheath is attached to a handle **44** that includes electrical connector **46**. The handle additionally includes a guide wire port **48**. The connector **46** is for interfacing with a power source, typically an RF generator **50**, and a microprocessor controller **52**. The power source and microprocessor controller are usually contained in one unit. The microprocessor controller controls the RF generator in response to external commands and data from a temperature sensor **54**, such as a thermocouple, or temperature sensors that may be positioned at an intraluminal venous treatment site.

The catheter **30** includes the expandable electrode device **56** that moves in and out of the outer sheath by way of the distal orifice **38** in this embodiment, although in other embodiments the device **56** may expand from and contract into the catheter **30** at other locations. The expandable electrode device **56** includes a plurality of electrodes **58** which can be expanded by moving the outer sheath **36** relative to the electrodes. Although FIG. **4** illustrates a plurality of electrodes **58** surrounding a single central electrode, different electrode configurations may be used.

Contained within the outer sheath **36** is an inner sheath **60** or inner member as shown in the cutaway portion of FIG. **4**.

A fluid port **62** communicates with the interior of the outer sheath. The catheter **30** can be periodically flushed out with saline through the fluid port. The flushing fluid can travel between the outer sheath and the inner sheath. The fluid port also allows for the delivery of drug therapies. Flushing out the catheter prevents the buildup of biological fluid, such as blood, within the catheter. The treatment area or site of the vein can be flushed with a fluid such as saline, or a high impedance dielectric fluid, in order to evacuate blood from the treatment area of the vein so as to prevent the formation of coagulum or thrombosis. The use of a high impedance dielectric fluid can minimize unintended heating effects away from the treatment area. The dielectric fluid directs the current of RF energy toward the vein wall. In addition, a vasoconstrictive agent may be applied to shrink the vein, heparin may be applied for coagulation avoidance, and a sclerosing agent may be applied to assist in ligation. These drugs or agents may be applied before, during, or after the catheter is used to heat the vein wall.

In one preferred embodiment, the catheter **30** includes a lumen which begins at the distal tip **55**, proximate the working end **40**, and runs substantially along the axis of the inner member before terminating at the guide wire port **48** of the handle **44**. A guide wire can be introduced through the lumen of the catheter for use in guiding the catheter to the desired treatment site. Where the catheter is sized to treat smaller veins, the outer diameter of the catheter may not allow for a fluid flush between the outer sheath and the inner sheath **60**. However, a fluid flush can be introduced through the guide wire port **48** in such an embodiment.

Turning again to FIG. **4**, an actuator **76** controls the extension of the electrode device **56** through the distal orifice **38**. The actuator may take the form of a switch, lever **78**, threaded control knob, or other suitable mechanism, and is preferably one that can provide fine control over the movement of the outer sheath **36** or the inner sheath **60**, as the case may be. In one embodiment of the invention, the actuator interfaces with the outer sheath to move it back and forth relative to the inner sheath. In another embodiment the actuator interfaces with the inner sheath to move it back and forth relative to the outer sheath. The relative position between the outer sheath and inner sheath is thus controlled, but other control approaches may be used.

In a preferred embodiment of a catheter **90** is illustrated in FIG. **5**. An inner member **92** or sheath is contained within the outer sheath **94**. The inner sheath is preferably constructed from a flexible polymer such as polymide, polyethylene, or nylon, and can travel the entire length of the catheter. The majority of the catheter should be flexible so as to navigate the tortuous paths of the venous system. A hypotube having a flared distal end **98** and a circular cross-sectional shape is attached over the distal end of the inner sheath **92**. The hypotube **96** is preferably no more than about two to three centimeters in length. The hypotube acts as part of a conductive secondary lead **100**. An uninsulated conductive electrode sphere **102** is slipped over the hypotube. The flared distal end of the hypotube prevents the electrode sphere from moving beyond the distal end of the hypotube. The sphere is permanently affixed to the hypotube, such as by soldering the sphere both front and back on the hypotube. The majority of the surface of the electrode sphere remains uninsulated. The remainder of the hypotube is preferably insulated so that the sphere-shaped distal end can act as the electrode. For example, the hypotube can be covered with an insulating material such as a coating of parylene. The interior lumen of the hypotube is lined by the inner sheath **92** which is attached to the flared distal end of the hypotube by adhesive such as epoxy.

Surrounding the secondary lead **100** are a plurality of primary leads **104** that preferably have a flat rectangular strip shape and can act as arms. In one configuration, the strip shape is a width from 0.76 mm (0.03 in) to 1.00 mm (0.04 in) and a thickness of approximately 0.13 mm (0.005 in.). As illustrated in FIG. **6**, the plurality of primary leads **104** is preferably connected to common conductive rings **106**. This configuration maintains the position of the plurality of primary leads, while reducing the number of internal electrical connections. The conductive rings **106** are attached to the inner sheath **92**. The position of the rings and the primary leads relative to the outer sheath **94** follows that of the inner sheath. As earlier described, the hypotube **96** of the secondary lead is also attached to the inner sheath. Two separate conductive rings can be used so that the polarity of different primary leads can be controlled separately. For example, adjacent primary leads can be connected to one of the two separate conductive rings so that the adjacent leads can be switched to have either opposite polarities or the same polarity. The rings are preferably spaced closely together, but remain electrically isolated from each other along the inner sheath. Both the rings and the hypotube are coupled with the inner sheath, and the primary leads that are connected to the rings move together with the secondary lead while remaining electrically isolated from the secondary lead. Epoxy or another suitable adhesive can be used to attach the rings to the inner sheath. The primary leads from the respective rings alternate with each other along the circumference of the inner sheath. The insulation along the underside of the leads prevents an electrical short between the rings. FIG. **6***a* illustrates an end view of the working end of catheter **90** taken along line **6***a*—**6***a* of FIG. **6**.

The conductive rings **106** and the primary leads **104** are attached together to act as cantilevers where the ring forms the base and the rectangular primary leads operate as the cantilever arms. The primary leads are formed to have an arc or bend such that the primary leads act as arms that tend to spring outwardly away from the catheter **90** and toward the surrounding venous tissue. Insulation along the underside of the primary leads and the conductive rings prevents unintended electrical coupling therebetween. Alternately, the primary leads are formed straight and connected to the conductive rings at an angle such that the primary leads tend to expand or spring radially outward from the conductive rings. The angle at which the primary leads are attached to the conductive rings should be sufficient to force the primary distal ends and their electrodes **108** through blood and into apposition with the vein wall **80** but not enough to preclude vein shrinkage. In particular, the primary leads **104** are formed with enough strength, and are mounted or bent such that they expand outwardly into apposition with the inner wall of the vein. However, the force they develop in an outward direction is not strong enough to prevent radial shrinkage of the vein. As the vein shrinks, due to the heating caused by the energy delivered by the electrodes **108**, the shrinking vein causes a contraction of the primary electrodes. Due to the outward force constantly exerted by the primary leads **104**, the electrodes **108** remain in constant apposition with the vein wall as it shrinks.

Other properties of the primary leads, such as lead shape and insulation thickness, affect the push force of the lead against the vein wall and the degree of arc or bend must be adjusted to compensate for these factors. The rectangular cross section of the primary leads can provide increased stability in the lateral direction while allowing the necessary bending in the radial direction. The primary leads are less likely to bend sideways when expanded outward due to the

increased size of the rectangular lead in that sideways direction, and a uniform spacing between primary leads is more assured. Uniform spacing between the primary leads and the distal ends promotes uniform heating around the vein by the electrodes **108**.

The distal ends of the primary leads **104** are uninsulated to act as the electrodes **108** having a rounded shape. In the embodiment shown, the shape is convex which may take the form of a spoon or hemispherical shape. The primary leads can be stamped to produce an integral shaped electrode at the distal end of the primary leads. The uninsulated outer portion of the distal end of the electrodes **108** which are to come into apposition with the wall of the vein is preferably rounded and convex. The flattened or non-convex inner portion of the distal end is insulated to minimize any unintended thermal effect, such as on the surrounding blood in a vein. The distal ends of the electrodes **108** are configured such that when the distal ends are forced toward the inner sheath **92**, as shown in FIG. **5***a*, the distal ends combine to form a substantially spherical shape with a profile smaller than the spherical electrode **102** at the secondary distal end.

In one preferred embodiment as shown in FIG. **6**, the electrodes **108** comprise a convex, square center section with semi-circular ends. It has been found that this "race track" configuration maximizes surface area of contact for the electrodes **108** shown.

The outer sheath **94** can slide over and surround the primary and secondary leads **100** and **104**. The outer sheath includes an orifice **110** which is dimensioned to have approximately the same size as the spherical electrode **102** at the secondary distal end. A close or snug fit between the spherical electrode **102** and the orifice **110** of the outer sheath is achieved. This configuration provides an atraumatic tip for the catheter **90**. The spherical electrode **102** is preferably slightly larger than the orifice **110**. The inner diameter of the outer sheath is approximately the same as the diameter of the reduced profile of the combined primary distal end electrodes **108**.

A fluid port (not shown) can communicate with the interior of the outer sheath **94** so that fluid can be flushed between the outer sheath and inner sheath **92** as described above. Alternately, a fluid port can communicate with a central lumen **112** in the hypotube which can also accept a guide wire for use in guiding the catheter to the desired treatment site. It is to be understood that another lumen can be formed in the catheter to deliver fluid to the treatment site. The delivered fluid displaces or exsanguinates blood from the vein so as to avoid heating and coagulation of blood. The delivery of a dielectric fluid increases the surrounding impedance so that RF energy is directed into the tissue of the vein wall. An alternate fluid could be a sclerosing agent which could serve to displace blood or to further enhance occlusion of the vein when applied before, during, or after energy delivery. The fluid can also include an anticoagulant such as heparin which can chemically discourage the coagulation of blood at the treatment site. The catheter **90** can be periodically flushed with saline which can prevent the buildup of biological fluid, such as blood, within the catheter. The saline can be flushed through the central lumen **112** or between the inner and outer sheaths. If a central lumen is not desired, the lumen of the hypotube can be filled with solder.

The electrode device **114** can operate in either a bipolar or a monopolar configuration. When adjacent primary leads have opposite polarity, a bipolar electrode operation is available. When the primary leads are commonly charged a monopolar electrode operation is available in combination with a large return electrode pad placed in contact with the patient. When the primary electrodes **108** are commonly charged or have a first potential, and a secondary electrode **102** has an opposite polarity or different potential, a bipolar electrode operation is available. More or fewer leads may be used. The number of leads can be dependent on the size or diameter of the vein to be treated, as described above.

Although not shown, it is to be understood that the catheter **90** can include one or more temperature sensors, such as thermocouples, mounted in place on an electrode **108** so that the sensor is substantially flush with the exposed surface of the electrode **108**. (The sensor is shown in a raised position in the drawings for clarity of illustration only). The temperature sensor senses the temperature of the portion of the vein that is in apposition with the exposed electrode **108** surface. The sensor provides an indication of when shrinkage occurs (70 degrees C. or higher). Application of RF energy from the electrodes **108** is halted or reduced when the monitored temperature reaches or exceeds the specific temperature that was selected by the operator, such as the temperature at which venous tissue begins to cauterize. Other techniques such as impedance monitoring and ultrasonic pulse echoing can be utilized in an automated system which shuts down or regulates the application of RF energy from the electrodes to the venous section when sufficient shrinkage of the vein **22** is detected. This also helps to forestall overheating of the vein.

Referring now to FIGS. **7** and **8**, in the operation of this embodiment of a catheter **90**, the catheter is inserted into a vein **22**. Fluoroscopy, ultrasound, an angioscope imaging technique, or another technique may be used to direct and confirm the specific placement of the catheter in the vein. Impedance measurements can also be used to determine proper positioning of the catheter, particularly at the ostium of a vessel such as at the sapheno-femoral junction. The impedance will be low when the electrodes are in the blood stream. The catheter can then be moved until a high impedance value is obtained, indicating electrode contact with the vein wall. The vein wall **80** has been compressed by the introduction of tumescent anesthesia into the tissue surrounding the vein as indicated by the arrows. The arrows in the figures indicate the compression of the tissue. Unless stated otherwise, all drawing figures having arrows indicating tissue compression are not drawn to scale for purposes of clarity of illustration and are meant to be representations of the vein in a nearly fully occluded state.

The reduction in the vein **22** diameter caused by the tumescence of the tissue in contact with the treatment site assists in pre-shaping the vein to be molded to a ligated state. The compression also exsanguinates the vein and forces blood away from the treatment site, thus preventing coagulation.

The actuator **76** (FIG. **4**) is then operated to retract the outer sheath **94** to expose leads the **100** and **104**. As the outer sheath no longer restrains the leads, the primary leads **104** move outward relative to the axis defined by the outer sheath, while the secondary lead **100** remains substantially linear along the axis defined by the outer sheath. The primary leads continue to move outward until their electrodes **108** are placed in apposition with the vein wall **80** and the outward movement of the primary leads is impeded. The primary electrodes **108** contact the vein wall along a generally circumferential area or band of the vein wall. This outward movement of the primary leads occurs in a substantially symmetrical fashion so that the primary electrodes

108 are substantially evenly spaced. Alternately, the electrodes 86 can be spaced apart in a staggered fashion such that they do not lie in the same plane. For example, the adjacent electrodes 86 can extend different lengths from the catheter so that a smaller cross-sectional profile is achieved when the electrodes 86 are collapsed toward one another.

When the electrodes 102 and 108 are positioned at the treatment site of the vein, the RF generator 50 is activated to provide suitable RF energy. One suitable frequency is 510 kHz. One criterion used in selecting the frequency of the energy to be applied is the control desired over the spread, including the depth, of the thermal effect in the venous tissue. Another criterion is compatibility with filter circuits for eliminating RF noise from thermocouple signals. In a bipolar operation, the primary electrodes 108 are charged with one polarity opposite that of the secondary electrode 102. The coupling between oppositely charged primary and secondary electrodes produces RF fields therebetween, and form a symmetrical RF field pattern along a circumferential band of the vein wall 80 to achieve a uniform temperature distribution along the vein wall being treated.

The RF energy produces a thermal effect which causes the venous tissue to shrink, reducing the diameter of the vein 22. The thermal effect produces structural transfiguration of the collagen fibrils in the vein. The collagen fibrils shorten and thicken in cross-section in response to the heat from the thermal effect. As shown in FIG. 8, the energy causes the vein wall 88 to collapse until further collapse is impeded by the primary lead electrodes 108. The primary lead electrodes are pressed closer together by the shrinking vein wall and assume a reduced profile shape which is sufficiently small so that the vein is effectively ligated.

The catheter 90 is pulled back while continuing energy delivery as shown in FIG. 9. Ligation as the catheter is being retracted produces a lengthy occlusion 89 which is stronger and less susceptible to recanalization than an acute point occlusion.

In a monopolar operation, the secondary-lead electrode 102 remains neutral, while the primary electrodes 108 are commonly charged and act in conjunction with an independent electrical device, such as a large low-impedance return pad (not shown) placed in external contact with the body, to form RF fields substantially evenly spaced around the circumference of the vein. The thermal effect produced by those RF fields along the axial length of the vein wall 80 causes the vein wall to collapse around the primary lead electrodes. The electrode device is retracted as described in the bipolar operation.

In either bipolar or monopolar operation the application of RF energy is substantially symmetrically distributed through the vein wall, as previously described. The electrodes should be spaced no more than 4 or 5 millimeters apart along the circumference of the vein wall 80, which defines the target vein diameter for a designed electrode catheter. Where the electrodes are substantially evenly spaced in a substantially symmetrical arrangement, and the spacing between the electrodes is maintained, a symmetrical distribution of RF energy increases the predictability and uniformity of the shrinkage and the strength of the occlusion.

Although not shown, in another embodiment, the primary leads may be mounted or otherwise configured such that they expand outwardly in an asymmetrical fashion. One purpose for an asymmetrical electrode arrangement is to only shrink a portion of the vein wall to achieve occlusion. Such may be desired in the case of preferentially shrinking a tributary branch or aneurysm on one side of the vein.

After completing the procedure for a selected venous section or treatment site, the actuator 76 causes the primary leads 104 to return to the interior of the outer sheath 94. Once the primary leads are within the outer sheath, the catheter 90 may be moved to another venous section where the ligation process is repeated.

As illustrated in FIGS. 10 and 11, another embodiment of an expandable electrode catheter 118 includes two sets of expandable electrode leads 120 and 122, although additional sets of electrode leads may be possible. The electrodes 124 of this embodiment are similar to the electrodes of the embodiment illustrated in FIG. 6 having electrodes with a rounded, convex, spoon-shaped contact area. Other shapes for the electrode may be used, such as ellipses, rounded, ovals, race tracks, and others. Although only one electrode is indicated by numeral 124 in FIGS. 10 and 11, this is for purposes of clarity in the drawings only. All electrodes are meant to be indicated by numeral 124. While each set of electrode leads may include as few as two electrode leads, the illustrated embodiment includes six electrode leads per set, although more than six electrode leads may be used as well.

In the embodiment shown in FIGS. 10 and 11, the sets of electrode leads 120 and 122 are longitudinally separated from each other. Thus, the electrodes within each set of electrode leads are separated from one another radially and each of those electrodes is also separated from every electrode in the other set longitudinally, due to the longitudinal separation. There therefore exists radial separation and longitudinal separation of electrodes at the working end 126 of the catheter 118 in the arrangement shown in FIGS. 10 and 11.

With the configuration of electrode leads presented in FIGS. 10 and 11, greater flexibility exists in establishing current flows through the tissue of a patient. As in previous embodiments, the electrodes expand outwardly into contact with patient tissue. Where all the electrodes of a first set of electrode leads have the same polarity, there may be an odd number of electrodes in the set, or an even number. All electrodes in the set may be connected to a common connection point, such as the conducting ring 106 shown in FIG. 6. A single conductor from the connecting end of the catheter may power all electrodes of the set by a single connection to that conducting ring. All electrodes of a second set of electrode leads may also be commonly connected at a respective conducting ring but to a different electrical potential than the first set. Because two different electrical potentials exist at the working end of the catheter, energy will flow through the patient tissue between those sets of electrode leads and a bipolar arrangement will exist. Thus, a length of patient tissue, at least as long as the distance between the first and second sets of electrode leads, will receive the energy.

A monopolar arrangement may also be established if desired by setting all electrodes of all electrode leads to the same electrical potential and establishing a different electrical potential outside the patient, such as at a "backplate" in contact with the skin of the patient at a selected location. Energy from the working end 126 of the catheter will then flow through the patient to the return provided by the backplate.

In another arrangement in polarizing or controlling the electrical potential at the electrodes, the electrodes in the first set of electrode leads may be individually controlled so that there are electrode pairs of differing potentials in the set of leads. This would establish a bipolar approach within the

first set of leads itself. If the electrodes of the second set of leads are likewise connected for different potentials among themselves, they too would provide a bipolar approach in their own set and currents would flow through patient tissue between the electrodes in each set of leads. If the electrodes having a first polarity in the first set are aligned with the electrodes having a different polarity in the second set of leads, energy would not only flow between the bipolar electrodes within the set but would also flow to the electrodes in the other set resulting in two bipolar arrangements at the single working end of the catheter. Patient tissue of a length at least as great as the distance between the first and second sets of electrode leads will receive energy as well as patient tissue between electrodes within each set of leads itself.

A further arrangement coupled with the bipolar approach just described would be to also use a backplate at a different electrical potential to provide further control over the energy flow through the patient's tissue. In this case, energy would flow between the electrodes within each set of leads, between electrodes in different sets of leads, and between electrodes and the backplate.

In yet a further arrangement, each of the electrodes may be individually connected to a power source (**50**, FIG. 4) and the electrical potential at each electrode can be individually controlled. This arrangement may yield even more precise control over the current densities through patient tissue. As an example, where less current flow is desired between certain electrodes of a set of leads but more current flow is desired between those electrodes and electrodes of a second set of leads, the potential between the electrodes of the same set may be reduced but the potential between those electrodes and the electrodes of the second set of leads may be increased resulting in the desired current flow densities. In the case where a backplate is also used, the electrodes may be controlled so that energy flows between such electrodes and the backplate. Because each electrode is individually controlled, the level of energy it imparts to the tissue at its location is controllable.

One factor that could affect the number of electrodes per set of electrode leads is the diameter of the vein being treated. The design of the contact pad for the electrode leads could also affect the desired number of electrodes for a given procedure.

In this embodiment, the electrode leads **120**, **122** are formed to expand outwardly into apposition with the target tissue, yet as the target tissue shrinks, the electrodes maintain contact with that tissue and are moved inwardly by that tissue. Because of this arrangement, the leads compensate for variations in the diameter of the vein. They are therefore capable of maintaining apposition with the tissue whether or not compression of the vein or anatomical structure exists, such as by use of a pressure cuff or tourniquet or tumescence of the surrounding tissue.

The tip **128** of the electrode catheter **118** should have a hemispherical or another atraumatic shape. The tip **128** may be electrically neutral, and may be fabricated from a polymer or it may be fabricated of stainless steel. Because the tip **128** has a rounded shape and is located at the distal extreme of the catheter, it may perform a guiding function when introducing the catheter to the patient.

The double set of expandable electrodes can be used to ligate veins or other hollow anatomical structures in a manner similar to that previously described. The outer sheath **130** can be pulled back to allow the electrode to expand outwardly from the catheter and into apposition with the wall of the lumen being treated. The two sets of electrodes **120** and **122** apply energy to the lumen to cause it to shrink to a reduced diameter. The catheter can be moved or pulled back while the energy is being applied to treat an extended area of the lumen. When the desired area of the lumen or vein is treated (e.g., ligated) energy is no longer provided to the electrodes, and the outer sheath **130** is pushed forward to force the expanded electrodes back to an unexpanded condition. The catheter can then be removed from the patient, or another section of the vein can be treated.

The description of the component parts discussed above are for a catheter to be used in a vein ranging in size from 3 mm (0.12 in) to 10 mm (0.39 in) in diameter. It is to be understood that these dimensions do not limit the scope of the invention and are merely exemplary in nature. The dimensions of the component parts may be changed to configure a catheter that may used in various-sized veins or other anatomical structures.

Referring now to FIG. **12**, there is shown a partial cross-section view of the catheter of FIGS. **10** and **11**. Two pluralities of electrodes **120** and **122** are shown with the electrodes of the first plurality **120** being indicated by numeral **124** and the electrodes of the second plurality **122** being indicated by numeral **150**. Each electrode is formed from an electrically-conductive electrode lead **152** and **154** respectively that is electrically insulated along its length except at its distal end at which point no insulation exists thus forming the electrode. Each lead has an outward bend (not shown). An inner tube **156** includes a lumen **158** through which fluid may flow for flush or other purposes, or through which a guide wire may be positioned. A hypotube **160** is positioned over the inner tube and layers of insulation **162** are mounted over the hypotube. The first plurality **120** of electrode leads **152** extend proximally to a first mounting ring **164** to which all are connected. The second plurality **122** of electrode leads **154** extend proximally to a second mounting ring **166** to which all are connected. The rings **164** and **166** are mounted over the hypotube insulation so that no electrical conduction path exists between the two. Wire conductors **168** and **170** extend from the proximal end of the catheter to each ring so that all electrode leads connected to a particular ring are interconnected electrically.

Alternate arrangements are possible and in one, alternating electrodes of a particular plurality are connected to two different rings. Each ring is separately connected to the power source and the polarities of the rings may therefore be made different to establish a bipolar approach within the plurality. One electrode may be a "+" polarity while the two adjacent electrodes may be a "−" polarity. In this case then, there would be a total of three rings for all electrodes. In another arrangement, both pluralities would have two rings for its respective electrodes with alternating electrodes connected to different rings so that bipolar approaches within each plurality may be established. In this case, there would exist a total of four rings for the two pluralities of electrodes.

An outer movable sheath **172** when slid in the distal direction to the point shown in FIG. **12** will cause the electrode leads to contract to the position shown. When slid in the proximal direction a sufficient distance, the sheath **172** acts as a deployment device in that it will move past the bend (not shown) in each of the electrode leads of the second plurality **122** permitting all electrode leads to expand outwardly as shown in FIG. **11**.

The electrode leads are formed of stainless steel in this embodiment and with the thin insulation layer and the

outward bend, have enough strength to automatically move outwardly through blood flow (in a venous application) and into apposition with the inner wall of the target tissue. As the inner wall shrinks due to the application of heat by the electrodes, the inner wall will force the electrode leads toward their contracted position but the electrodes will automatically stay in apposition with the inner wall during the entire ligation process due to their outward bends and the material of which they are formed.

In one embodiment shown in FIG. **12**, the electrode **124** includes a temperature sensor **54** and an electrode of the second plurality also includes a temperature sensor **54**. Although not shown as such, they are mounted flush with the outer electrode surfaces and their wires protrude inwardly through the electrode and are held in place along the respective leads **152** and **154**. In one embodiment, the microprocessor **52** (FIG. **4**) receives the signals from both temperature sensors, averages those signals and determines the effective temperature at the treatment site based on that average signal. Methods of averaging temperature signals are well known to those skilled in the art and no further description is provided here.

Although described above as positively charged, negatively charged, or as a positive conductor or negative conductor, these terms are used for purposes of illustration only. These terms are generally meant to refer to different electrode potentials and are not meant to indicate that any particular voltage is positive or negative. Furthermore, other types of energy such as light energy from fiber optics can be used to create a thermal effect in the hollow anatomical structure undergoing treatment. Additionally, although the electrodes and leads have been described as protruding from a distal orifice in the catheter, they may be expanded by other means and in other configurations. In another embodiments, the leads may be deployed by an inner pull wire, hydraulics, or magnetic fields.

The benefits of tumescence would include locally anesthetizing the treatment area for a prolonged period of time and insulating most of the surrounding tissue and nerves from the damage of heat conducting from the treated vein. An additional benefit of the vasoconstriction induced by the Epinephrine would be that the constricted blood vessels would limit how fast the body absorbed the Lidocaine thus keeping the level of Lidocaine absorbed below the toxicity level. Also, as mentioned supra, extended applications of energy have a greater possibility of increasing the temperature of the blood to an unacceptable level and may result in a significant amount of heat-induced coagulum forming on the electrode and in the vein which is not desirable. Using a tumescent anesthesia compression technique, including the administration of vasocontrictive drugs, would aid in preventing this problem by exsanguinating the vein.

Although described above in terms of a vein, the concepts are generally applicable to other hollow anatomical structures in the body as well. The above description has been generally confined to veins in consideration of avoiding unnecessary repetition.

While several particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A method of applying energy to a hollow anatomical structure comprising the steps of:

introducing a catheter having a working end into the hollow anatomical structure;

positioning the working end of the catheter at a treatment site within the hollow anatomical structure;

administering a fluid into the tissue near the treatment site to cause swelling and compress the hollow anatomical structure to a reduced size around the catheter; and

applying energy to the hollow anatomical structure at the treatment site from the working end of the catheter such that the hollow anatomical structure durably assumes a reduced size to effectively occlude the hollow anatomical structure.

2. The method of claim **1** further comprising the step of moving the working end of the catheter along the hollow anatomical structure during the step of applying energy.

3. The method of claim **1** further comprising the steps of:

ceasing the step of applying energy;

moving the working end of the catheter to a new treatment site along the hollow anatomical structure;

applying energy to the hollow anatomical structure at the new treatment site from the working end of the catheter.

4. The method of claim **1** wherein the step of applying energy includes the step of applying electrical energy.

5. The method of claim **1** wherein the step of applying energy includes the step of applying RF energy.

6. The method of claim **1** wherein the step of applying energy includes the step of applying microwave energy.

7. The method of claim **1** wherein the step of applying energy includes the step of applying light energy.

8. The method of claim **1** wherein the step of applying energy includes the step of applying thermal energy.

9. The method of claim **1** wherein the fluid thermally insulates the tissue near the treatment site.

10. The method of claim **1** wherein the fluid thermally insulates nerve tissue near the treatment site.

11. The method of claim **1** wherein the fluid limits thermal damage to the tissue near the treatment site during the step of applying energy.

12. A method of applying energy to a hollow anatomical structure comprising the steps of:

introducing a catheter having a working end with an energy application device at the working end into the hollow anatomical structure;

positioning the working end of the catheter at the treatment site within the hollow anatomical structure;

administering a fluid into the tissue near the treatment site to cause swelling and compress the hollow anatomical structure to a reduced size around the catheter; and

applying energy to the hollow anatomical structure at the treatment site via the energy application device such that the hollow anatomical structure durably assumes a reduced size to effectively occlude the hollow anatomical structure, wherein the fluid limits the thermal effect on the tissue near the treatment site from heat generated during the step of applying energy.

13. The method of claim **12** wherein the tissue near the treatment site includes nerves.

14. The method of claim **12** further comprising the step of moving the energy application device along the hollow anatomical structure during the step of applying energy.

15. The method of claim 12 further comprising the steps of:

ceasing the step of applying energy;

moving the energy application device to a new treatment site along the hollow anatomical structure;

applying energy to the hollow anatomical structure at the new treatment site via the energy application device.

16. The method of claim 12 wherein the step of applying energy includes the step of applying electrical energy circumferentially from within the hollow anatomical structure.

17. The method of claim 12 wherein the step of applying energy includes the step of applying RF energy.

18. The method of claim 12 wherein the step of applying energy includes the step of applying microwave energy.

19. The method of claim 12 wherein the step of applying energy includes the step of applying light energy.

20. The method of claim 12 wherein the step of applying energy includes the step of applying thermal energy.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

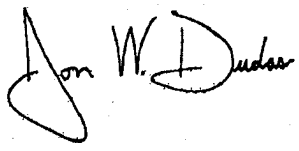
PATENT NO. : 6,752,803 B2
DATED : June 22, 2004
INVENTOR(S) : Michael P. Goldman et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,
Item [56], **References Cited**, FOREIGN PATENT DOCUMENTS, delete "0 189 327" and insert in its place -- 0 189 329 --

Signed and Sealed this

Twenty-sixth Day of July, 2005



JON W. DUDAS
Director of the United States Patent and Trademark Office

EXHIBIT 2

US006769433B2

(12) **United States Patent**
Zikorus et al.

(10) **Patent No.: US 6,769,433 B2**
(45) **Date of Patent: Aug. 3, 2004**

(54) **EXPANDABLE VEIN LIGATOR CATHETER HAVING MULTIPLE ELECTRODE LEADS, AND METHOD**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/866,517**

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(65) **Prior Publication Data**

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Related U.S. Application Data

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(51) **Int. Cl.**[7] **A61F 5/56**

(52) **U.S. Cl.** **128/898**; 606/41

(58) **Field of Search** 606/27–29, 31, 606/32, 34, 41, 42; 607/46, 98, 100–102, 104–106; 128/898

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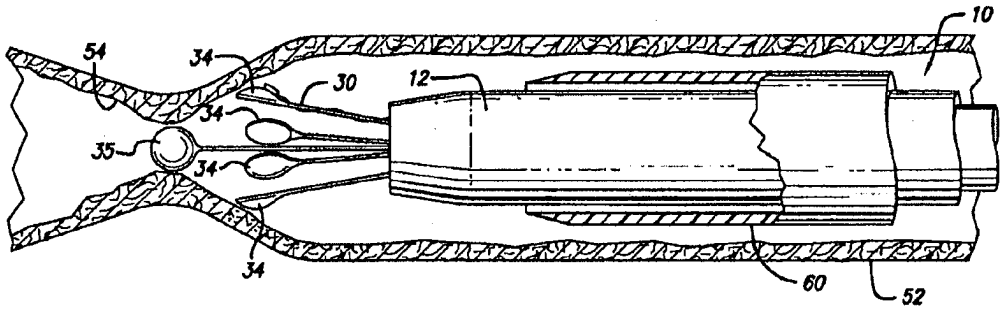
(57) **ABSTRACT**

A catheter includes a plurality of primary leads to deliver energy for ligating a hollow anatomical structure. Each of the primary leads includes an electrode located at the working end of the catheter. Separation is maintained between the primary leads such that each primary lead can individually receive power of selected polarity. The primary leads are constructed to expand outwardly to place the electrodes into apposition with an anatomical structure. High frequency energy can be applied from the leads to create a heating effect in the surrounding tissue of the anatomical structure. The diameter of the hollow anatomical structure is reduced by the heating effect, and the electrodes of the primary leads are moved closer to one another. Where the hollow anatomical structure is a vein, energy is applied until the diameter of the vein is reduced to the point where the vein is occluded. In one embodiment, a secondary lead is surrounded by the primary leads, and extends beyond the primary leads. The secondary lead includes an electrode at the working end of the catheter. The secondary lead can have a polarity opposite to the polarity of the primary leads in a bipolar configuration. The polarity of the leads can be switched and the catheter can be moved during treatment to ligate an extended length of the vein. The catheter can include a lumen to accommodate a guide wire or to allow fluid delivery.

64 Claims, 10 Drawing Sheets



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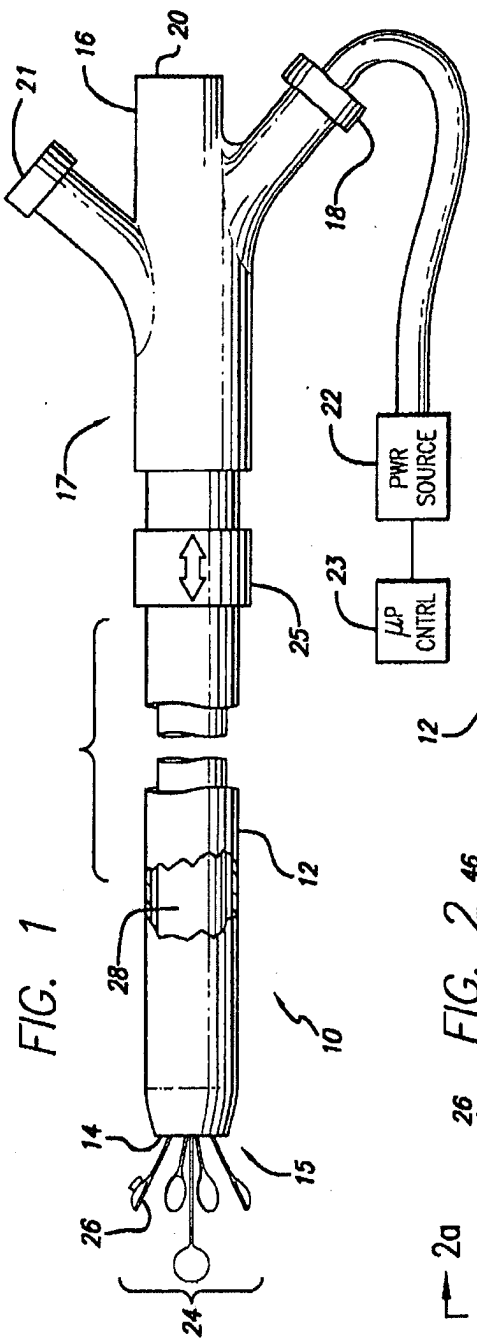

FIG. 1

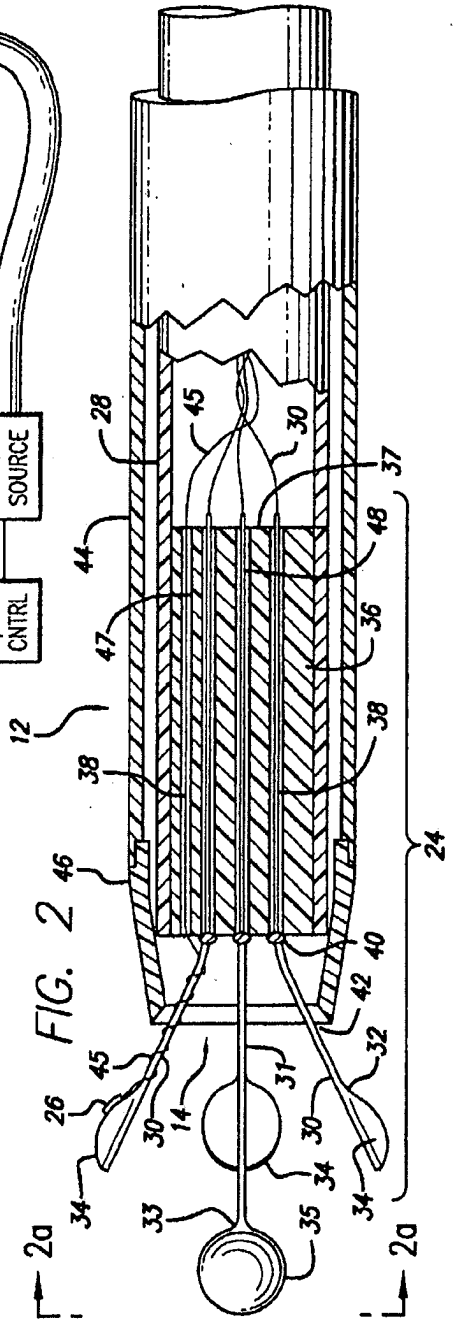

FIG. 2

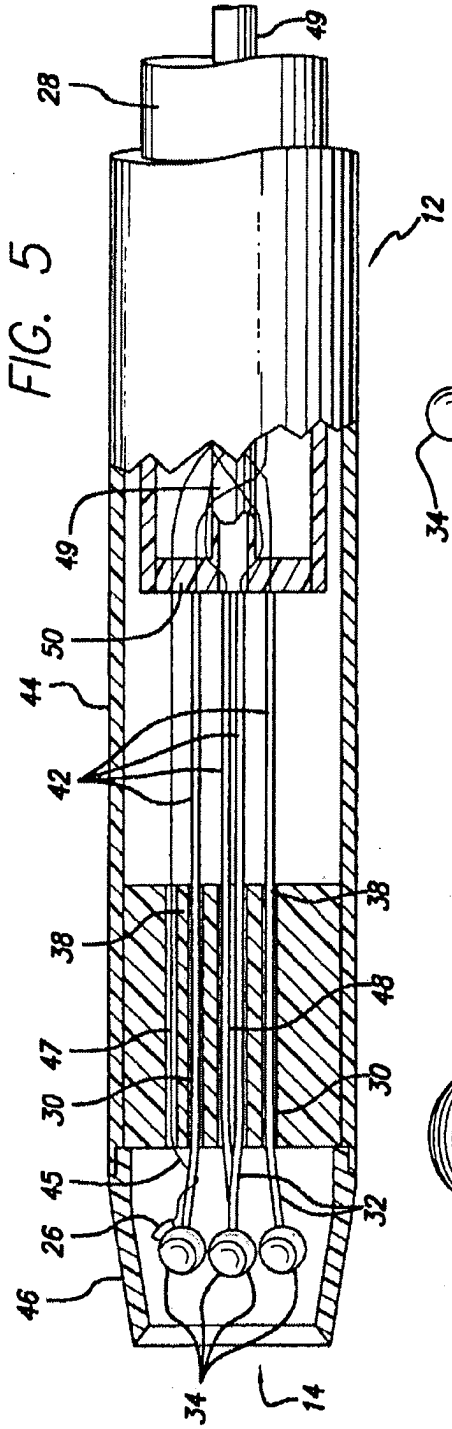

FIG. 5

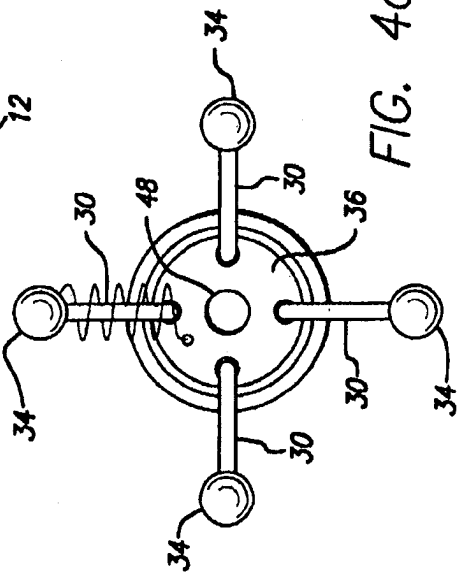

FIG. 4a

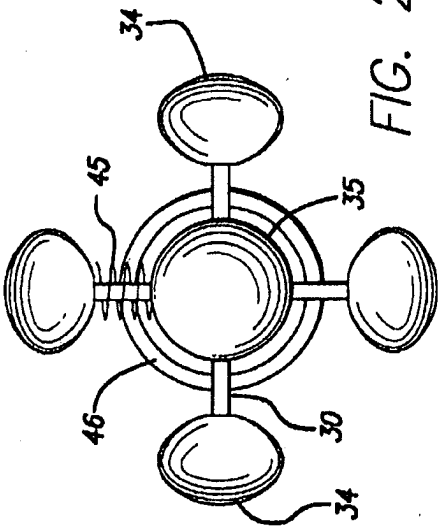

FIG. 2a

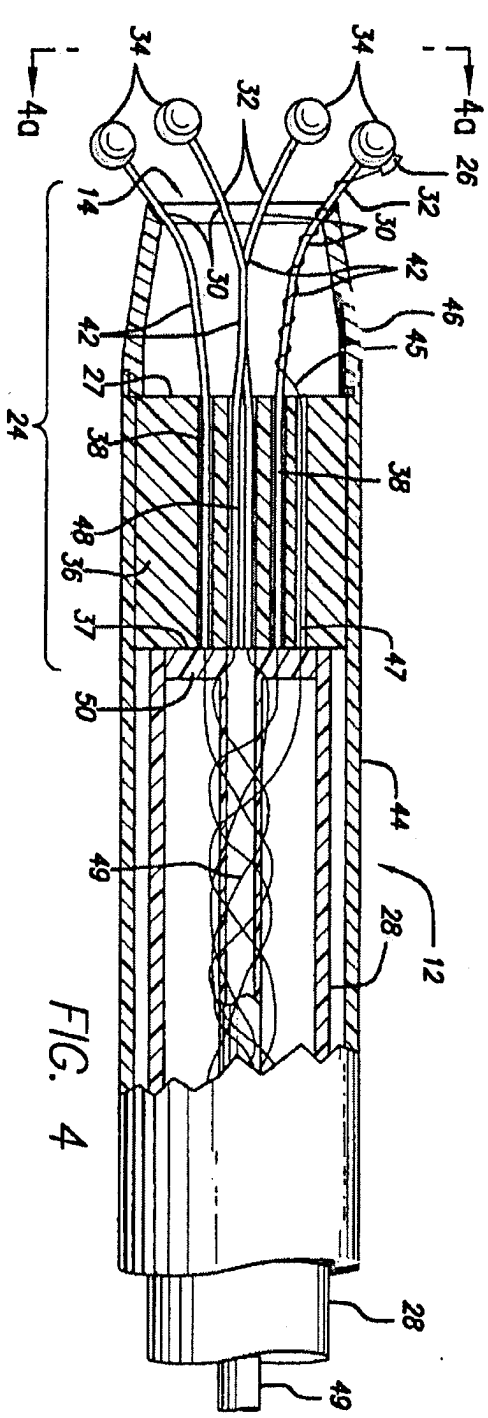
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FIG. 3

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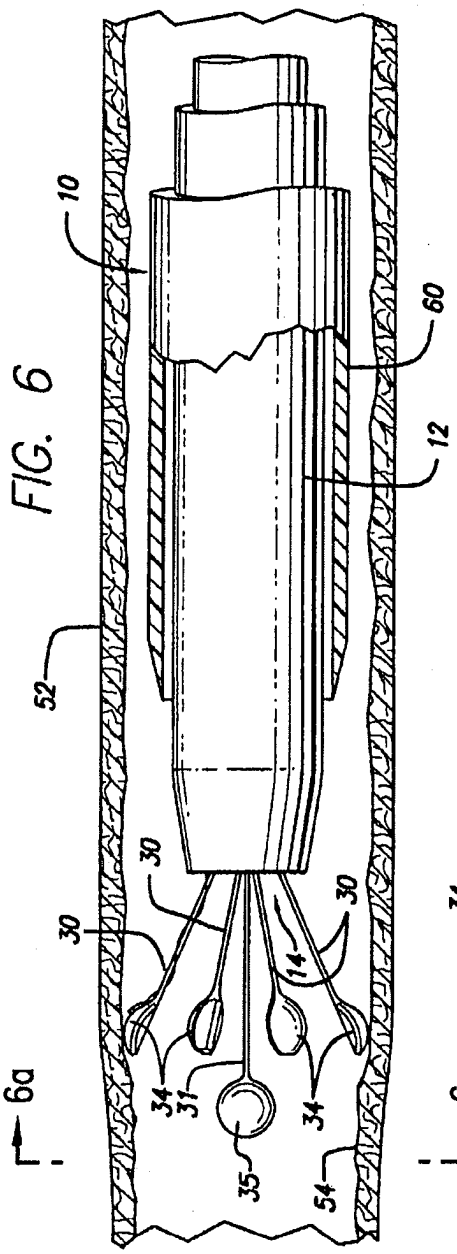
FIG. 4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6a

FIG. 6

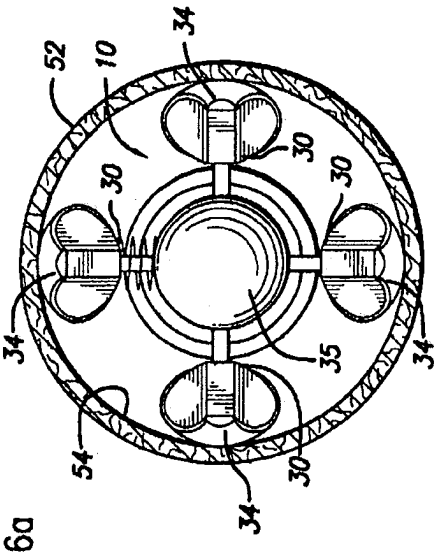
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FIG. 6a

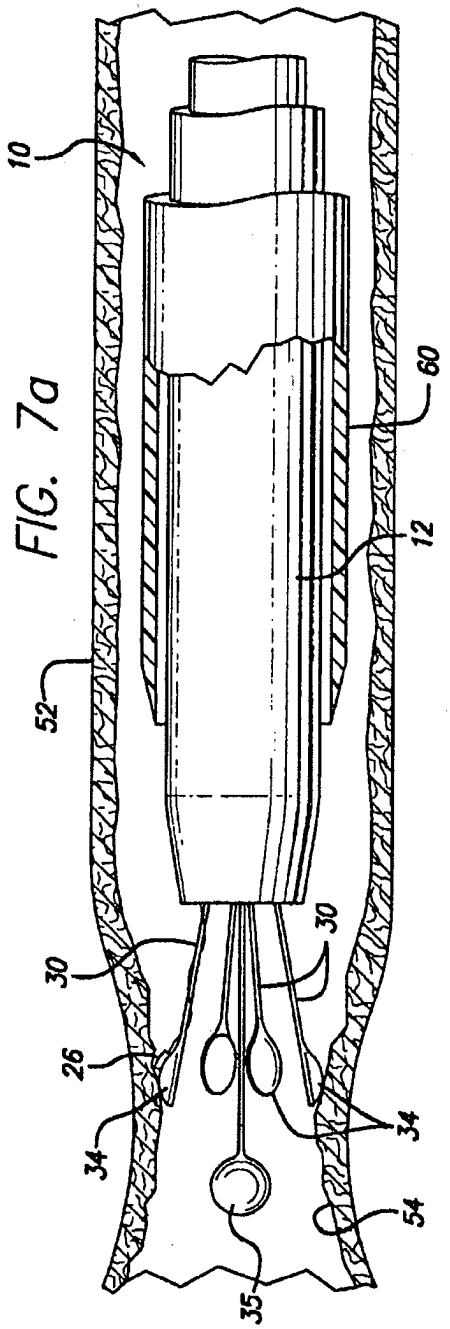

FIG. 7a

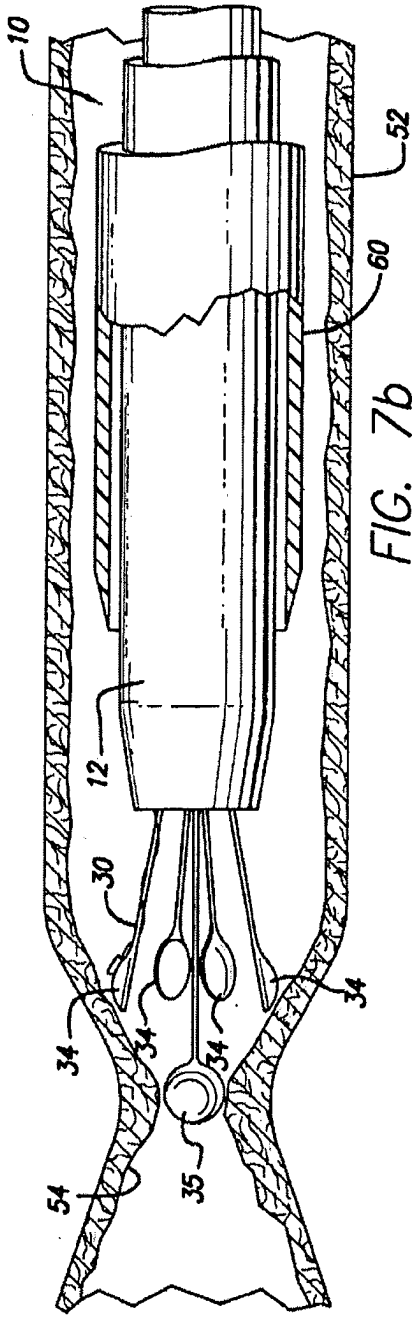

FIG. 7b

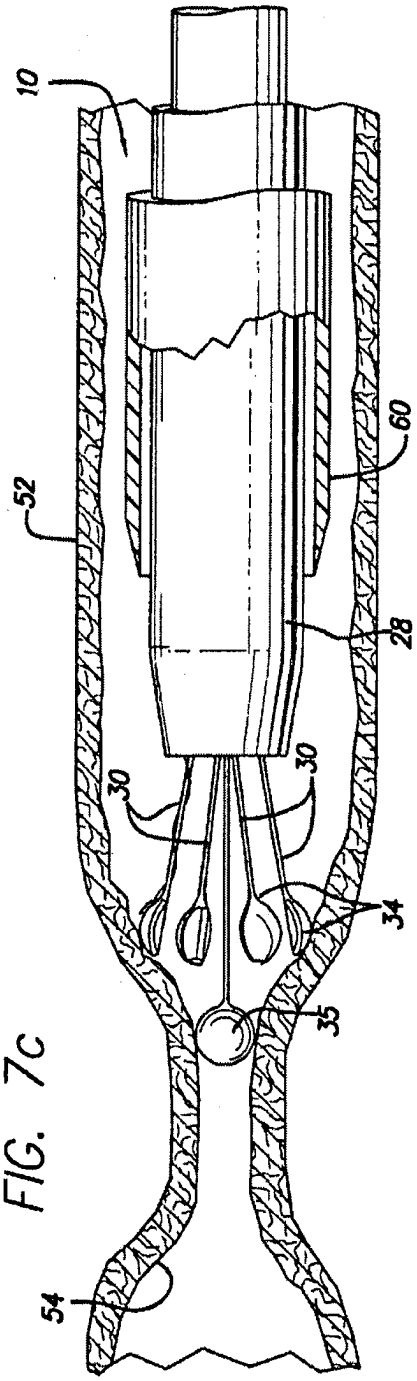

FIG. 7c

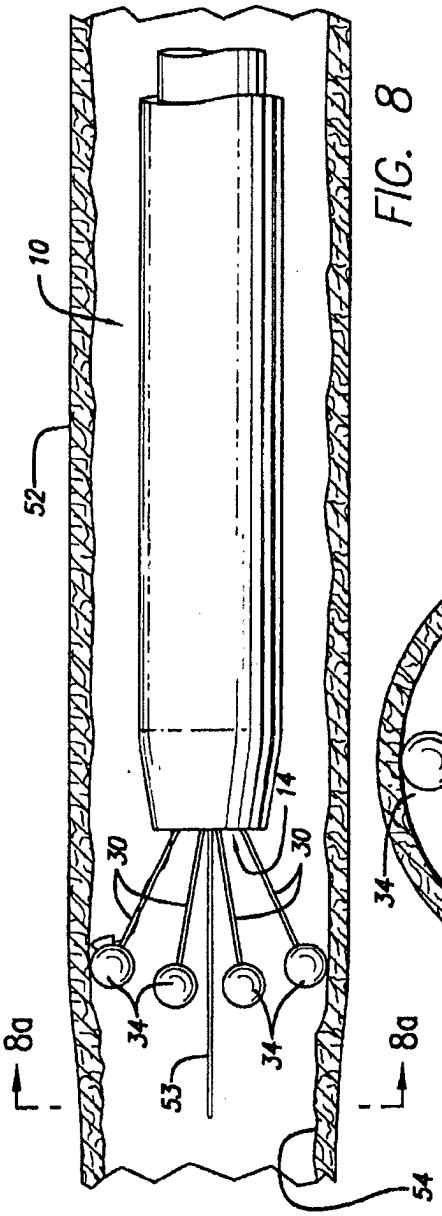

FIG. 8

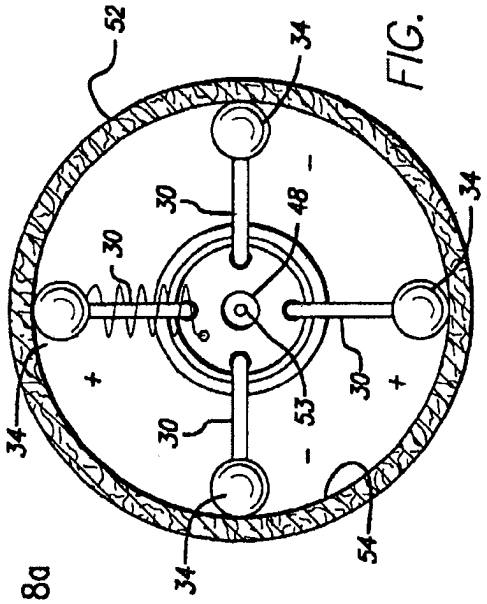

FIG. 8a

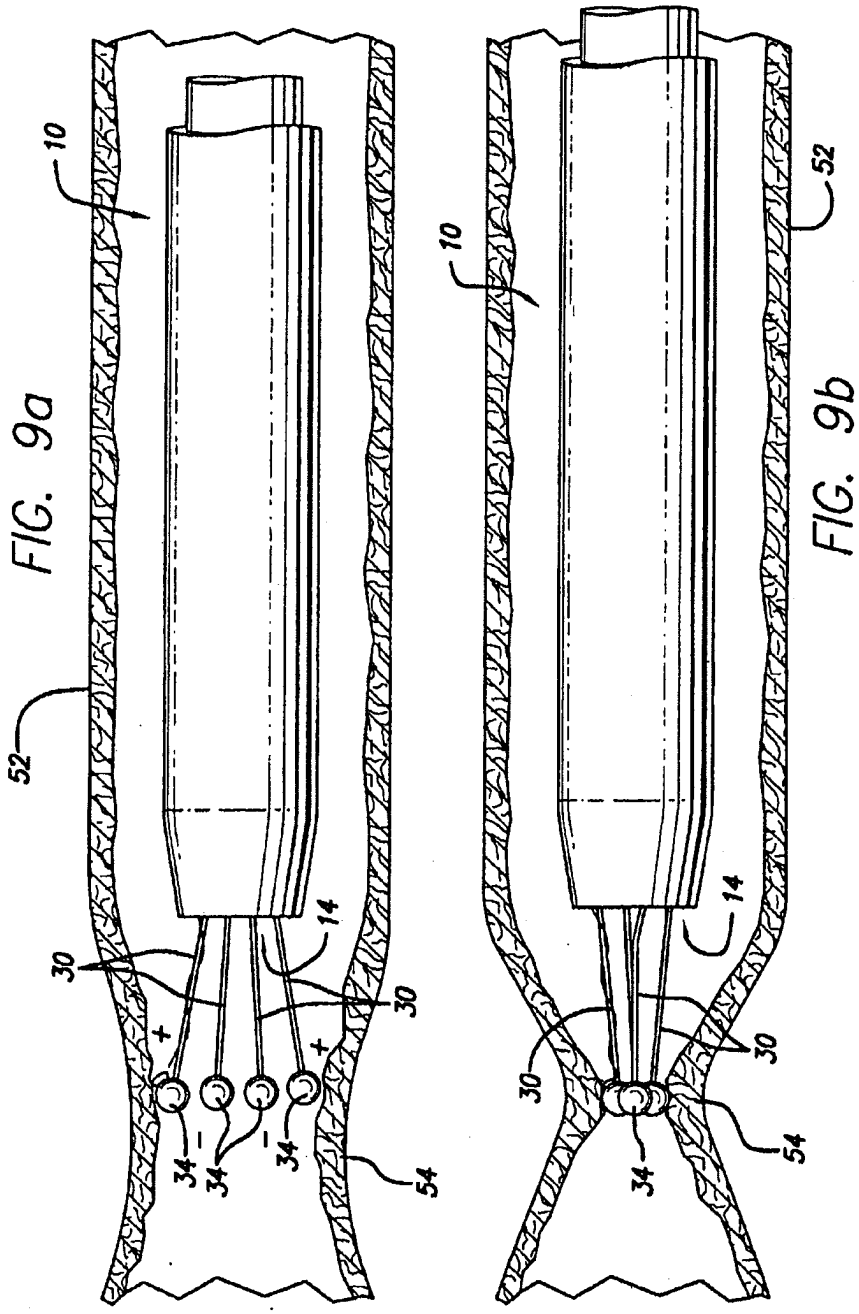
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FIG. 9a
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FIG. 9b

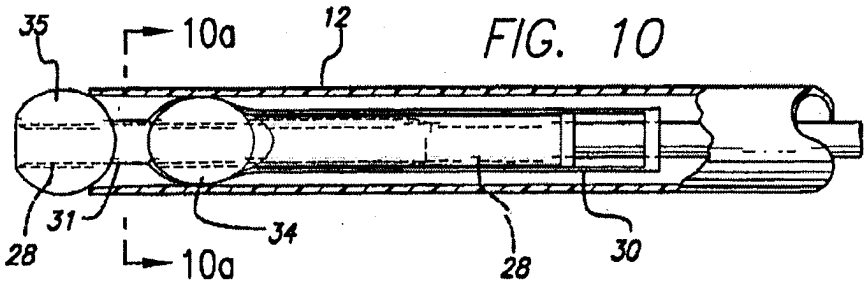


FIG. 10

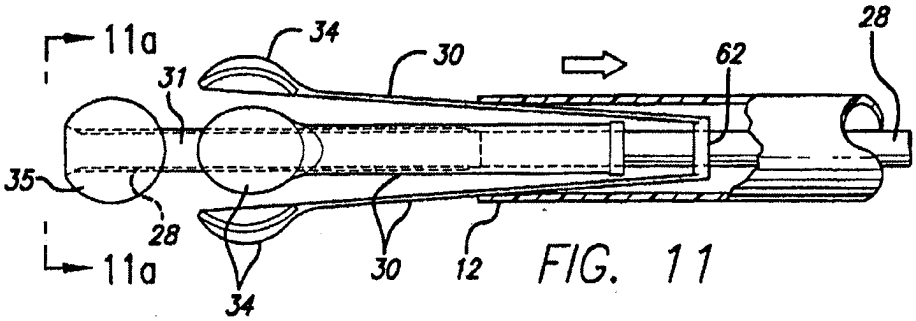


FIG. 11

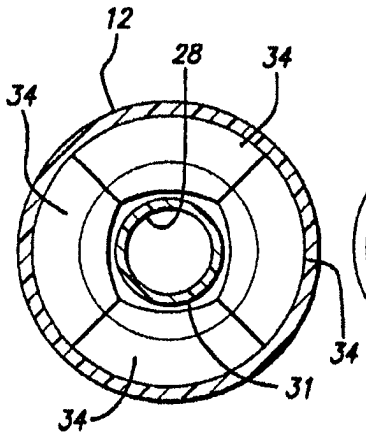


FIG. 10a

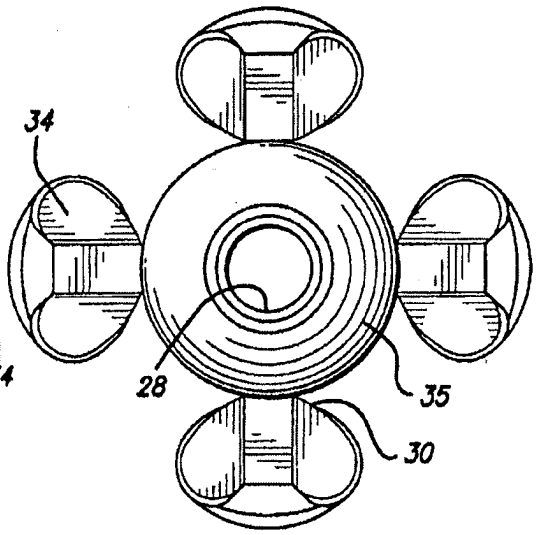


FIG. 11a

FIG. 12

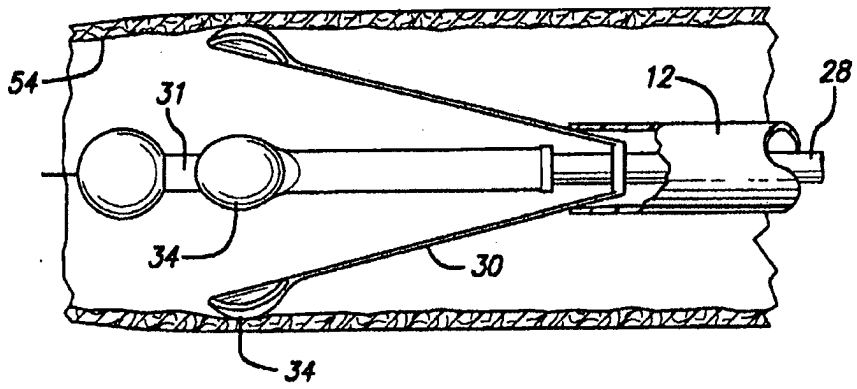
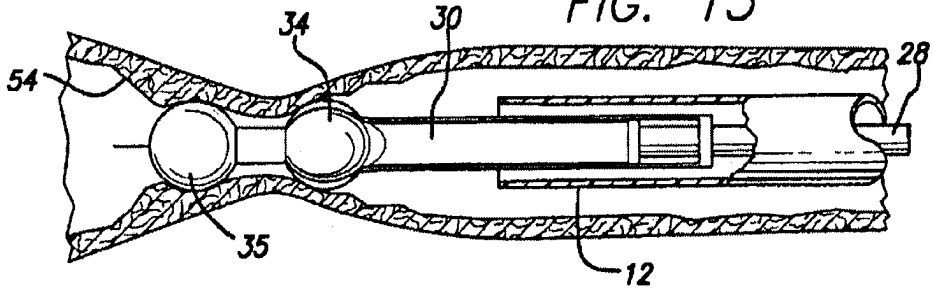


FIG. 13



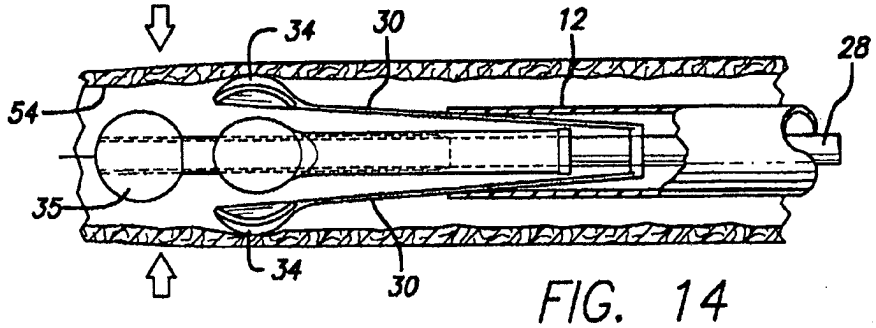


FIG. 14

EXPANDABLE VEIN LIGATOR CATHETER HAVING MULTIPLE ELECTRODE LEADS, AND METHOD

This application is a continuation of application Ser. No. 09/267,756 filed Mar. 10, 1999, now U.S. Pat. No. 6,237,606 which is a divisional of application Ser. No. 08/927,251 filed on Sep. 11, 1997, now U.S. Pat. No. 6,200,312.

BACKGROUND OF THE INVENTION

The invention relates generally to a method and apparatus for applying energy to shrink a hollow anatomical structure such as a vein, and more particularly, to a method and apparatus using an electrode device having multiple leads for applying said energy.

The human venous system of the lower limbs consists essentially of the superficial venous system and the deep venous system with perforating veins connecting the two systems. The superficial system includes the long or great saphenous vein and the short saphenous vein. The deep venous system includes the anterior and posterior tibial veins which unite to form the popliteal vein, which in turn becomes the femoral vein when joined by the short saphenous vein.

The venous system contains numerous one-way valves for directing blood flow back to the heart. Venous valves are usually bicuspid valves, with each cusp forming a sack or reservoir for blood which, under retrograde blood pressure, forces the free surfaces of the cusps together to prevent retrograde flow of the blood and allows only antegrade blood flow to the heart. When an incompetent valve is in the flow path, the valve is unable to close because the cusps do not form a proper seal and retrograde flow of the blood cannot be stopped. When a venous valve fails, increased strain and pressure occur within the lower venous sections and overlying tissues, sometimes leading to additional valvular failure. Two venous conditions which often result from valve failure are varicose veins and more symptomatic chronic venous insufficiency.

The varicose vein condition includes dilation and tortuosity of the superficial veins of the lower limbs, resulting in unsightly discoloration, pain, swelling, and possibly ulceration. Varicose veins often involve incompetence of one or more venous valves, which allow reflux of blood within the superficial system. This can also worsen deep venous reflux and perforator reflux. Current treatments of vein insufficiency include surgical procedures such as vein stripping, ligation, and occasionally, vein-segment transplant.

Ligation involves the cauterization or coagulation of vascular lumina using electrical energy applied through an electrode device. An electrode device is introduced into the vein lumen and positioned so that it contacts the vein wall. Once properly positioned, RF energy is applied to the electrode device thereby causing the vein wall to shrink in cross-sectional diameter. A reduction in cross-sectional diameter, as for example from 5 mm (0.2 in) to 1 mm (0.04 in), significantly reduces the flow of blood through the vein and results in an effective ligation. Though not required for effective ligation, the vein wall may completely collapse thereby resulting in a full-lumen obstruction that blocks the flow of blood through the vein.

One apparatus for performing venous ligation includes a tubular shaft having an electrode device attached at the distal tip. Running through the shaft, from the distal end to the proximal end, are electrical leads. At the proximal end of the shaft, the leads terminate at an electrical connector, while at

the distal end of the shaft the leads are connected to the electrode device. The electrical connector provides the interface between the leads and a power source, typically an RF generator. The RF generator operates under the guidance of a control device, usually a microprocessor.

The ligation apparatus may be operated in either a monopolar and bipolar configuration. In the monopolar configuration, the electrode device consists of an electrode that is either positively or negatively charged. A return path for the current passing through the electrode is provided externally from the body, as for example by placing the patient in physical contact with a large low-impedance pad. The current flows from the ligation device to the low impedance pad. In a bipolar configuration, the electrode device consists of a pair of oppositely charged electrodes separated by a dielectric material. Accordingly, in the bipolar mode, the return path for current is provided by the electrode device itself. The current flows from one electrode, through the tissue, and returns by way of the oppositely charged electrode.

To protect against tissue damage; i.e., charring; due to cauterization caused by overheating, a temperature sensing device is attached to the electrode device. The temperature sensing device may be a thermocouple that monitors the temperature of the venous tissue. The thermocouple interfaces with the RF generator and the controller through the shaft and provides electrical signals to the controller which monitors the temperature and adjusts the energy applied to the tissue, through the electrode device, accordingly.

The overall effectiveness of a ligation apparatus is largely dependent on the electrode device contained within the apparatus. Monopolar and bipolar electrode devices that comprise solid devices having a fixed shape and size limit the effectiveness of the ligating apparatus for several reasons. Firstly, a fixed-size electrode device typically contacts the vein wall at only one point on the circumference or inner diameter of the vein wall. As a result, the application of RF energy is highly concentrated within the contacting venous tissue, while the flow of RF current through the remainder of the venous tissue is disproportionately weak. Accordingly, the regions of the vein wall near the point of contact collapse at a faster rate then other regions of the vein wall, resulting in non-uniform shrinkage of the vein lumen. Furthermore, the overall strength of the occlusion may be inadequate and the lumen may eventually reopen. To avoid an inadequate occlusion RF energy must be applied for an extended period of time. Application of RF energy as such increases the temperature of the blood and usually results in a significant amount of heat-induced coagulum forming on the electrode and in the vein which is not desirable.

Secondly, the effectiveness of a ligating apparatus having a fixed electrode device is limited to certain sized veins. An attempt to ligate a vein having a diameter that is substantially greater than the electrode device can result in not only non-uniform shrinkage of the vein wall as just described, but also insufficient shrinkage of the vein. The greater the diameter of the vein relative to the diameter of the electrode device, the weaker the energy applied to the vein wall at points distant from the point of contact. Accordingly the vein wall is likely to not completely collapse prior to the venous tissue becoming over cauterized at the point of electrode contact. While coagulation as such may initially occlude the vein, such occlusion may only be temporary in that the coagulated blood may eventually dissolve and the vein partially open. One solution for this inadequacy is an apparatus having interchangeable electrode devices with various diameters. Such a solution, however, is both economically inefficient and tedious to use.

Hence those skilled in the art have recognized a need for an expandable electrode device and a method capable of evenly distributing RF energy along a circumferential band of a vein wall where the vein wall is greater in diameter than the electrode device, and thereby provide more predictable and effective occlusion of veins while minimizing the formation of heat-induced coagulum. The invention fulfills these needs and others.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention provides an apparatus and method for applying energy along a generally circumferential band of a vein wall. The application of energy as such results in a more uniform and predictable shrinkage of the vein wall.

In one aspect of the invention, an apparatus for delivering energy to ligate an anatomical structure comprises a catheter having a sheath, a working end, and an opening formed at the working end of the catheter; an inner member disposed within the sheath such that the inner member and the sheath are capable of being moved relative to one another; a plurality of leads, each lead having a distal end, the plurality of leads being coupled with the inner member such that the distal ends of the plurality of leads extend out of the opening at the working end of the catheter when the position of the sheath changes in one direction relative to the inner member, each lead being formed to move the distal end away from a longitudinal axis defined by the sheath when the plurality of leads are extended out the opening; wherein the distal ends of the leads are configured to deliver energy to the anatomical structure.

In another aspect of the invention, the apparatus includes a secondary lead having a secondary distal end. The secondary lead is coupled with the inner member such that the distal end of the secondary lead is extended out of the opening at the working end of the catheter when the position of the inner member changes in one direction relative to the sheath.

In another aspect of the invention, the distal ends of the leads are electrically connected to a power source such that the polarity of each lead can be switched. Where there is a secondary lead electrode, the plurality of leads can be connected to the power source such that the polarity of the leads can be changed independently of the polarity of the secondary lead.

In another aspect, the leads include primary leads which generally surround the secondary lead at the working end of the catheter. The distal ends of the primary leads are located between the distal end of the secondary lead and the inner member.

In yet another aspect, the invention comprises a method of applying energy to a hollow anatomical structure from within the structure. The method includes the step of introducing a catheter into the anatomical structure; the catheter having a working end and a plurality of leads, each lead having a distal end, and each lead being connected to a power source. The method also includes the step of expanding the leads outwardly through the distal orifice and expanding the leads until each electrode contacts the anatomical structure. The method further includes the step of applying energy to the anatomical structure from the distal end of the leads, until the anatomical structure collapses.

In another aspect of the invention, the method also includes the step of introducing a catheter into the anatomical structure where the catheter has a secondary lead that has a distal portion that is greater in length than the primary-lead distal portions and is generally surrounded by the primary leads. The secondary lead also has an electrode at the distal end. The method also includes the steps of extending the primary and secondary leads through the orifice until each primary-lead electrode contacts the anatomical structure, and controlling the power source so that adjacent primary leads are of opposite polarity while maintaining the secondary lead so that it is electrically neutral. Upon collapse of the anatomical structure around the primary leads, the polarity of the primary leads is switched so that they are all of the same polarity. Upon switching the polarity of the primary leads so that they are of the same polarity, controlling the power source so that the secondary lead is of opposite polarity relative to the primary leads. The method, in a further aspect, comprises the step of moving the catheter in the anatomical structure while continuing to apply energy to the anatomical structure to lengthen the area of ligation.

In another aspect of the invention, external compression is used to initially force the wall of the vein to collapse toward the catheter. The application of energy molds the vein to durably assume the collapsed state initially achieved mechanically by the external compression. A tourniquet can be used to externally compress or flatten the anatomical structure and initially reduce the diameter of the hollow anatomical structure. The pressure applied by the tourniquet can exsanguinate blood from the venous treatment site, and pre-shape the vein in preparation to be molded to a ligated state. An ultrasound window formed in the tourniquet can be used to facilitate ultrasound imaging of the anatomical structure being treated through the window.

These and other aspects and advantages of the present invention will become apparent from the following more detailed description, when taken in conjunction with the accompanying drawings which illustrate, by way of example, embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a diagram of an energy application system with a partial cutaway view of a catheter showing both the working end and the connecting end and incorporating a preferred embodiment of the present invention;

FIG. **2** is a cross-sectional view of the working end of a first embodiment of a catheter in accordance with the invention depicting the electrodes in a fully extended position;

FIG. **2***a* is an end view of the working end of the first embodiment of the catheter taken along line **2***a*—**2***a* of FIG. **2**;

FIG. **3** is a cross-sectional view of the working end of the first embodiment depicting the electrodes in a fully retracted position;

FIG. **4** is a cross-sectional view of the working end of a second catheter in accordance with principles of the invention depicting the electrodes in a fully extended position;

FIG. **4***a* is an end view of the second embodiment of the invention taken along line **4***a*—**4***a* of FIG. **4**;

FIG. **5** is a cross-sectional view of the working end of the second embodiment of the catheter of FIG. **4** depicting the electrodes in a fully retracted position;

FIG. **6** is a cross-sectional view of an anatomical structure containing the catheter of FIG. **2** with the electrodes in apposition with the anatomical structure;

FIG. **6***a* is an end view of the anatomical structure containing the catheter taken along line **6***a*—**6***a* of FIG. **6**;

FIGS. **7***a* through **7***c* are cross-sectional views of the anatomical structure containing a catheter in accordance

with the first embodiment of the invention and depicting the anatomical structure at various stages of ligation;

FIG. **8** is a cross-sectional view of an anatomical structure containing a catheter in accordance with the second embodiment of the invention as depicted in FIG. **4**;

FIG. **8***a* is an end view of the anatomical structure containing the catheter taken along line **8***a*—**8***a* of FIG. **8**; and

FIGS. **9***a* and **9***b* are cross-sectional views of the anatomical structure containing the catheter in accordance with the second embodiment of the invention and depicting the anatomical structure at various stages of ligation;

FIG. **10** is a cross-sectional view of the working end of a third embodiment of a catheter in accordance with the invention depicting the electrodes in a fully extended position;

FIG. **10***a* is an end view of the working end of the third embodiment of the catheter taken along line **10***a*—**10***a* of FIG. **10**;

FIG. **11** is a cross-sectional view of the working end of the third embodiment depicting the electrodes in a fully retracted position;

FIG. **11***a* is a view taken along line **11***a***14** **11***a* of FIG. **11**

FIG. **12** is a cross-sectional view of an anatomical structure containing the catheter of FIG. **10** with the electrodes in apposition with the anatomical structure;

FIG. **13** is a cross-sectional view of the anatomical structure containing the catheter of FIG. **10** where the anatomical structure is being ligated by the application of energy from the electrodes.

FIG. **14** is a cross-sectional view of an anatomical structure containing the catheter of FIG. **10** with the electrodes in apposition with the anatomical structure where external compression is being applied to reduce the diameter of the hollow structure before the application of energy from the electrodes to ligate the structure.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Turning now to the drawings with more particularity wherein like reference numerals indicate like or corresponding elements among the figures, shown in FIG. **1** is a catheter **10** for applying energy to an anatomical structure such as a vein. The catheter **10** includes an outer sheath **12** having a distal orifice **14** at its working end **15**. The connector end **17** of the outer sheath **12** is attached to a handle **16** that includes an electrical connector **18** for interfacing with a power source **22**, typically an RF generator, and a microprocessor controller **23**. The power source **22** and microprocessor **23** are usually contained in one unit. The controller **23** controls the power source **22** in response to external commands and data from a sensor, such as a thermocouple, located at an intraluminal venous treatment site. In another embodiment, the user can select a constant power output so that automated temperature control is not present and the user can manually adjust the power output in view of the temperature on a display readout. The catheter **10** includes an expandable electrode device **24** (partially shown) that moves in and out of the outer sheath **12** by way of the distal orifice **14**. The electrode device includes a plurality of electrodes which can be expanded by moving the electrodes within the shaft, or by moving the outer shaft relative to the electrodes. Although FIG. **1** illustrates a plurality of electrodes surrounding a single central electrode, different electrode configurations will be described for the catheter.

Contained within the outer sheath **12** is an inner sheath **28** or inner member. A fluid port **21** communicates with the interior of the outer sheath **12**. The catheter **10** can be periodically flushed out with saline through the port **21**. The flushing fluid can travel between the outer sheath and the inner sheath. The port also allows for the delivery of drug therapies. Flushing out the catheter prevents the buildup of biological fluid, such as blood, within the catheter **10**. The treatment area of the hollow anatomical structure such as a vein can be flushed with a fluid such as saline, or a dielectric fluid, in order to evacuate blood from the treatment area of the vein so as to prevent the formation of coagulum or thrombosis. The use of a dielectric fluid can minimize unintended heating effects away from the treatment area. The dielectric fluid prevents the current of RF energy from flowing away from the vein wall.

In one embodiment, the catheter **10** includes a lumen which begins at the distal tip of the outer sheath **12** and runs substantially along the axis of the outer sheath **12** before terminating at the guide-wire port **20** of the handle **16**. A guide wire can be introduced through the lumen of the catheter **10** for use in guiding the catheter to the desired treatment site. Where the catheter is sized to treat smaller veins, the outer diameter of the catheter may not allow for a fluid flush between the outer sheath **12** and the inner sheath **28**. However, a fluid flush can be introduced through the lumen for the guide wire in such an embodiment.

Referring now to FIGS. **2**, **2***a*, **3**, **4**, **4***a* and **5**, the outer sheath **12** includes a shell **44** and a tip portion **46**. To provide an atraumatic tip for the catheter **10** as it is manipulated through the vein, the tip **46** is preferably tapered inward at its distal end or is "nosecone" shaped. The tip **46**, however, can have other shapes that facilitate tracking of the catheter **10** over a guide wire and through the bends in the venous vascular system. The nosecone-shaped tip **46** can, for example, be fabricated from a polymer having a soft durometer, such as 70 Shore A. The shell **44** comprises a biocompatible material having a low coefficient of friction. In one configuration, the outer sheath **12** is sized to fit within a venous lumen and for example may be between 5 and 9 French, which corresponds to a diameter of between 1.7 mm (0.07 in) and 3.0 mm (1.2 in), or other sizes as appropriate.

The electrode device **24** contains a number of leads, including insulated primary leads **30** and, in some embodiments, a secondary lead **31**. Preferably, the leads are connected to the power source **22** (FIG. **1**) such that the polarity of the leads may be switched as desired. Alternately, a microprocessor controller can be used to switch the polarity, as well as control other characteristics of the power for the electrode device. Thus the electrode device can operate in either a bipolar or a monopolar configuration. When adjacent primary leads **30** have opposite polarity the electrode device **24** operates as a bipolar electrode device. When the primary leads **30** are commonly charged the electrode device **24** can operate as a monopolar electrode device. When the primary leads **30** are commonly charged, and a secondary lead **31** has an opposite polarity, the electrode device **24** operates as a bipolar electrode device. The embodiment of the invention shown in FIGS. **2** and **3** depict an electrode device **24** having four primary leads **30** and a secondary lead **31**, while the embodiment of the invention shown in FIGS. **4** and **5** depict an electrode device **24** having only four primary leads. The invention is not limited to four primary leads **30**; more or fewer leads may be used in either embodiment. The number of leads can be dependent on the size or diameter of the hollow anatomical structure to be treated. The apposed electrodes should be

kept within a certain distance of one another. Larger vessels may require more primary leads to ensure proper current density and proper heat distribution.

The insulation on each of the leads **30, 31** may be removed at the distal end **32, 33** to expose the conductive wire. In the first configuration as shown in FIGS. **2, 2***a*, and **3**, the electrode **34** has a hemispherical shape. In a second configuration, the electrode can have either a generally spherical shape or a spoon shape. As shown in FIGS. **4, 4***a* and **5**, the electrodes have a spoon shape which can be combined to form a sphere or other shape so as to minimize its profile when the vein collapses. The electrodes **34** are either integrally formed at the distal end **32**, soldered, or otherwise formed to the distal end of each primary lead **30**. It is to be understood that when the distal end **32** is referred to as acting as an electrode, this is not limited to where the electrode **34** is integrally formed at the distal end **32**. For example, the distal end can apply energy to the surrounding tissue where there is an electrode integrally formed at the distal end, or where an electrode is separately soldered to the distal end, or where there is another energy delivery device located at the distal end. The electrode **34** typically has a diameter greater than the diameter of the primary lead **30**. For example, the primary lead **30** may have a diameter ranging from 0.18 mm (0.007 in.) to 0.28 mm (0.011 in.), while the electrode **34** has a diameter of 0.36 mm (0.014 in.) to 0.51 mm (0.020 in.). The primary leads **30** and the electrodes **34** are preferably made from a biologically-compatible material such as stainless steel. The insulation surrounding the primary leads **30** generally has a thickness of between 0.03 mm (0.001 in.) and 0.06 mm (0.0025 in.), resulting in a combined lead-insulation diameter of between 0.23 mm (0.009 in.) and 0.41 mm (0.016 in.). In an alternate configuration, as shown in FIGS. **2** and **3**, each primary lead **30** is strip-shaped with a width from 0.76 mm (0.03 in.) to 1.0 mm (0.04 in) and a thickness of approximately 0.13 mm (0.005 in.), while the secondary lead **31** is typically tubular-shaped. It should be noted that these dimensions are provided for illustrative purposes, and not by way of limitation. A hemispherically shaped electrode **34** is formed at the distal end, as for example, by sanding down a sixteenth-inch (1.6 mm) diameter sphere which is soldered to the distal end **32** of the primary lead **30**. The electrodes can also be constructed by stamping the desired shape or configuration from the conductive lead. The electrode is integral with the lead, and the remainder of the lead is insulated. The distal end **33** of the secondary lead **31** preferably includes a generally spherically-shaped electrode **35**.

An alignment device **36** arranges the leads **30, 31** such that they are mounted to the catheter at only their proximal ends and so that separation is maintained between the leads within, and distal to the alignment device. The leads can form cantilevers when mounted on the alignment device. A preferred configuration of the alignment device **36** includes a plurality of off-center, axially-aligned lumina **38** which are substantially symmetrically positioned relative to the axis of the alignment device **36**. The alignment device **36** is formed, for example, by extruding the plurality of axially-aligned lumina **38** through a solid cylinder composed of a dielectric material, such as polyamide. Each lead **30** passes through an individual off-center lumen **38** and exits out the rear of the alignment device **36**. The alignment device **36** may further include a central lumen **48** that may be aligned with the axis. In some embodiments the central lumen **48** is used for accepting a guide wire or for the delivery or perfusion of medicant and cooling solution to the treatment area during application of RF energy. In other embodiments, the central lumen **48** may be used for the secondary lead **31**. The alignment device **36** may also further include an auxiliary lumen **47** for additional leads, such as the leads of a thermocouple used as a temperature sensor. The alignment device **36** comprises a dielectric material to prevent or minimize any coupling effect the leads **30, 31** may have with each other and, if present, the guide wire. The length of the alignment device is, for example, 12.5 mm (0.5 in.) to 19.0 mm (0.75 in.) in one embodiment. However, these dimensions are provided for purposes of illustration and not by way of limitation.

In the embodiment of the invention shown in FIGS. **2, 2***a* and **3**, the inner sheath **28** is attached to the alignment device **36** and extends beyond the rear **37** of the alignment device. Preferably, the inner sheath **28** completely surrounds the exterior wall of the alignment device **36** and is mounted to it by adhesive or press fit or in other manner such that it remains in a fixed position relative to the inner sheath. The inner sheath and alignment device can act as an inner member relative to the outer sheath. The inner sheath **28** comprises a biocompatible material with a low coefficient of friction. The inner sheath **28** provides a pathway for the interconnection between the leads **30, 31** and the electrical connector **18** (FIG. **1**). This interconnection may occur in any of several ways. The leads **30, 31** themselves may be continuous and run the entire length of the inner sheath **28**. In the alternative (not shown), the positively charged leads **30, 31** may couple with a common positively charged conductor housed in the inner sheath **28**. Likewise, the negatively charged leads **30, 31** may couple with a common negative conductor. Preferably, the leads **30, 31** are connected to a conductor that allows for the polarity of the leads to be switched. The conductor may comprise, for example, a 36 gauge copper lead with a polyurethane coating. The coupling may occur at any point within the inner sheath **28**. To reduce the amount of wire contained in the catheter, it is advantageous to couple the leads **30, 31** at the point where the leads exit the rear **37** of the alignment device **36**. To add further stability to the electrode device **24**, it is preferred that bonding material **40** surround the leads **30, 31** at the front end of the alignment device **36**. In this embodiment, the leads **30, 31** exit through the distal orifice **14** as the outer sheath **12** is retracted backwards over the alignment device **36**. The inwardly tapered tip **46** impedes the retracting movement of the outer sheath **12** to prevent the exposure of the alignment device **36**.

FIG. **3** shows the leads **30** and **31** in the retracted position where all leads are within the nosecone-shaped tip portion **46** and the outer shell **44**. The alignment device **36** has been moved relative to the outer shell **44**. The soft nosecone provides an atraumatic tip for when the catheter is maneuvered through the tortuous venous system. The electrode at the distal end of the secondary lead **31** can be sized to approximately the same size as the opening formed in the nosecone **46**. The nosecone forms a closed atraumatic tip together with the electrode of the secondary lead when the alignment device is retracted into the outer sheath of the catheter. This can present an atraumatic tip even where the nosecone is not constructed from a material having a soft durometer.

Referring now to FIGS. **4** and **5**, in another embodiment, the alignment device **36** is attached to the outer sheath **12** and thereby remains immobile in relation to it. The inner sheath **28** is movably positioned at the rear of the alignment device **36** and again provides a pathway for the interconnection between the primary leads **30** and the electrical connector **18** (FIG. **1**). In some embodiments the inner

sheath **28** contains a guide-wire tube **49** that runs the entire length of the inner sheath. The guide-wire tube **49** is aligned to communicate with the central lumen **48** of the alignment device **36** at one end and with the guide-wire port **20** (FIG. **1**) at the other end. The primary leads **30** may be continuous and run the entire length of the inner sheath **28** or they may be coupled to common leads as previously described. The primary leads **30** are secured to the front end **27** of the inner sheath **28**, as for example with a potting material **50**, so that the movement of the inner sheath **28** results in a corresponding movement of the primary leads **30** through the lumina **38** of the alignment device **36**. In this embodiment, the primary leads **30** are not secured to the alignment device **36** and in essence are free-floating leads in the axial direction. The primary leads **30** travel through the alignment device **36** and exit through the distal orifice **14** as the front end of the inner sheath **28** is moved toward the rear **37** of the alignment device **36**.

In the above embodiments, the primary leads **30** are formed, e.g., arced or bent, to move away from each other and thereby avoid contact. The "distal portion" of the primary leads **30** is the portion of the lead which extends from the front end of the alignment device **36** when the leads are fully extended through the distal orifice **14**. It is preferred that the distal portions **42** are formed to move radially outward from each other relative to the axis of the alignment device **36** and form a symmetrical arrangement. This is shown in both the embodiments of FIG. **2***a* and FIG. **4***a*. The degree of arc or bend in the primary leads **30** may be any that is sufficient to radially expand the leads as they exit the outer sheath **12** through the distal orifice **14**. It is essential that the degree of the arc or bend be sufficient to provide enough force so that the primary leads **30** expand through blood and the electrodes **34** come in apposition with the vein wall. The electrodes are preferably partially embedded in the vein wall to assure full contact. The rounded portion of the electrode is embedded into the vein wall to achieve full surface apposition so that the entire uninsulated surface area of the electrode is in contact with venous tissue for effective current distribution. The surface area of the electrodes in contact with the venous tissue preferably is sufficient to avoid a high current density which may lead to spot heating of the venous tissue. The heating effect is preferably distributed along a circumferential band of the vein. The apposed electrodes should be spaced no more than 4 or 5 millimeters from one another along the circumference of the vein. Thus, the electrode arrangement is related to the size or diameter of the vein being treated. Other properties of the primary leads **30**, such as lead shape and insulation thickness, affect the push force of the lead and the degree of arc or bend must be adjusted to compensate for these factors. For example, in one configuration of the electrode device **24**, a wire having a diameter of between 0.18 mm (0.007 in) and 0.28 mm (0.011 in) with a total insulation thickness of between 0.05 mm (0.002 in) to 0.13 mm (0.005 in) is arced or bent at an acute angle to provide sufficient apposition with the anatomical structure. It is to be understood that these dimensions are provided for illustrative purposes, and not by way of limitation.

Other techniques for expanding the leads outwardly once they have been extended from the working end of the catheter may be possible. For example, the leads may be straight but are mounted in the alignment device at an angle such that they are normally directed outward.

For increased appositional force, it is preferred that the primary leads **30** be strip-shaped, that is rectangular in cross section, with dimensions, for example, of a width from 0.76 mm (0.030 in.) to 1.0 mm (0.039 in) and a thickness of approximately 0.13 mm (0.005 in.). The rectangular cross section provides increased resistance to bending in the width dimension but allows bending more freely in the thickness dimension. This strip-shaped configuration of the primary leads **30** is shown in FIGS. **2**, **2***a*, and **3** and provides for increased stability in the lateral direction while allowing the necessary bending in the radial direction. In FIGS. **2**, **2***a*, and **3**, each primary lead comprises a rectangular cross section mounted in relation to the catheter such that the thinner dimension of the rectangular cross section is aligned with the direction of expansion of the lead. The leads are less likely to bend sideways when expanded outward, and a uniform spacing between leads is more assured. Uniform spacing promotes uniform heating around the venous tissue which is in apposition with the electrodes at the distal ends of the leads.

The length of the distal portion of the leads **30** also affects the configuration of the electrode device **24**. The maximum distance between two mutually opposed electrodes **34**; i.e., the effective diameter of the electrode device **24**, is affected by the bend degree and length of the distal portion **42**. The longer the length of the distal portion **42** the greater the diameter of the electrode device **24**. Accordingly, by changing the distal portion **42** length and arc or bend degree, the catheter **10** can be configured for use in differently sized anatomical structures.

Different numbers of leads **30**, **31** can be employed with the catheter. The number of leads **30**, **31** is limited by the diameter of the alignment device **36** and the number of lumina **36**, **38**, **47** that can be extruded through the alignment device. In a bipolar configuration, an even number of primary leads **30** are preferably available to form a number of oppositely charged electrode pairs. The electrodes in appostion with the anatomical structure should be maintained within a certain distance of each other. In a monopolar configuration, any number of commonly charged leads **30** can be present. In the monopolar mode, distribution of RF energy through the anatomical tissue is obtained by creating a return path for current through the tissue by providing a return device at a point external from the tissue, such as a large metal pad.

Now referring again to FIG. **1**, an actuator **25** controls the extension of the electrode device **24** through the distal orifice **14**. The actuator **25** may take the form of a switch, lever, threaded control knob, or other suitable mechanism, and is preferably one that can provide fine control over the movement of the outer sheath **12** or the inner sheath **28**, as the case may be. In one embodiment of the invention, the actuator **25** (FIG. **1**) interfaces with the outer sheath **12** (FIGS. **2**, **2***a* and **3**) to move it back and forth relative to the inner sheath **28**. In another embodiment the actuator **25** (FIG. **1**) interfaces with the inner sheath **28** (FIGS. **4**, **4***a* and **5**) to move it back and forth relative to the outer sheath **12**. The relative position between the outer sheath and inner sheath is thus controlled, but other control approaches may be used.

Referring again to FIGS. **2**, **2***a*, **3**, **4**, **4***a* and **5**, the catheter **10** includes a temperature sensor **26**, such as a thermocouple. The temperature sensor **26** is mounted in place on an electrode **34** so that the sensor **26** is nearly or is substantially flush with the exposed surface of the electrode **34**. The sensor **26** is shown in the drawings as protruding from the electrodes for clarity of illustration only. The sensor **26** senses the temperature of the portion of the anatomical tissue that is in apposition with the exposed electrode surface. Monitoring the temperature of the anatomical tissue

provides a good indication of when shrinkage of the tissue is ready to begin. A temperature sensor **26** placed on the electrode facing the anatomical tissue provides an indication of when shrinkage occurs (70° C. or higher) and when significant amounts of heat-induced coagulum may begin to form on the electrodes (at 85° C. or higher). Therefore maintaining the temperature above 70 degrees Centigrade produces a therapeutic shrinkage of the anatomical structure. Application of the RF energy from the electrodes **34** is halted or reduced when the monitored temperature reaches or exceeds the specific temperature that was selected by the operator, typically the temperature at which anatomical tissue begins to cauterize. The temperature sensor **26** interfaces with the controller **23** (FIG. **1**) through a pair of sensor leads **45** which preferably run through the auxiliary lumen **47** and then through the inner sheath **28**. The signals from the temperature sensor **26** are provided to the controller **23** which controls the magnitude of RF energy supplied to the electrodes **34** in accordance with the selected temperature criteria and the monitored temperature. Other techniques such as impedance monitoring, and ultrasonic pulse echoing can be utilized in an automated system which shuts down or regulates the application of RF energy from the electrodes to the venous section when sufficient shrinkage of the vein is detected and to avoid overheating the vein.

Referring now to FIGS. **6**, **6***a* and **7***a* through **7***c*, in the operation of one embodiment of the catheter **10**, the catheter is inserted into a hollow anatomical structure, such as a vein **52**. The catheter is similar to the embodiment discussed in connection with FIGS. **2** and **3**. The catheter **10** further includes an external sheath **60** through which a fluid can be delivered to the treatment site. In this embodiment, the fluid port (not shown) communicates with the interior of the external sheath **60**, and fluid is delivered from between the external sheath **60** and the outer sheath **12**. The external sheath **60** surrounds the outer sheath **12** to form a coaxial channel through which fluid may be flushed.

Fluoroscopy, ultrasound, an angioscope imaging technique, or other technique may be used to direct the specific placement of the catheter and confirm the position in the vein. The actuator (not shown) is then operated to shift the outer sheath relative to the inner sheath by either retracting the outer sheath **12** backward or advancing the inner sheath **28** forward to expose the leads **30**, **31** through the distal orifice **14**. As the leads **30**, **31** exit the distal orifice **14**, the primary leads **30** expand radially outward relative to the axis of the alignment device **36**, while the secondary lead **31** remains substantially linear. The primary leads **30** continue to move outward until apposition with the vein wall **54** occurs and the outward movement of the primary leads **30** is impeded. The primary leads **30** contact the vein along a generally circumferential band of the vein wall **54**. This outward movement of the primary leads **30** occurs in a substantially symmetrical fashion. As a result, the primary-lead electrodes **34** are substantially evenly spaced along the circumferential band of the vein wall **54**. The central-lead electrode **35** is suspended within the vein **52** without contacting the vein wall **54**.

When the electrodes **34** are positioned at the treatment site of the vein, the power supply **22** is activated to provide suitable RF energy, preferably at a selected frequency from a range of 250 kHz to 350 MHZ. One suitable frequency is 510 kHz. One criterion used in selecting the frequency of the energy to be applied is the control desired over the spread, including the depth, of the thermal effect in the venous tissue. Another criterion is compatibility with filter circuits for eliminating RF noise from thermocouple signals.

In bipolar operation, the primary leads **30** are initially charged such that adjacent leads are oppositely charged while the secondary lead is electrically neutral. These multiple pairs of oppositely charged leads **30** form active electrode pairs to produce an RF field between them. Thus, discrete RF fields are set up along the circumferential band of the vein wall **54**. These discrete fields form a symmetrical RF field pattern along the entire circumferential band of the vein wall **54**, as adjacent electrodes **34** of opposite polarity produce RF fields between each other. A uniform temperature distribution can be achieved along the vein wall being treated.

The RF energy is converted within the adjacent venous tissue into heat, and this thermal effect causes the venous tissue to shrink, reducing the diameter of the vein. A uniform temperature distribution along the vein wall being treated avoids the formation of hot spots in the treatment area while promoting controlled uniform reduction in vein diameter. The thermal effect produces structural transfiguration of the collagen fibrils in the vein. The collagen fibrils shorten and thicken in cross-section in response to the heat from the thermal effect. As shown in FIG. **7***a*, the energy causes the vein wall **54** to collapse around the primary-lead electrodes **34**. The wall **54** continues to collapse until further collapse is impeded by the electrodes **34**. The electrodes are pressed farther and farther together by the shrinking vein wall **54** until they touch and at that point, further collapse or ligation of the wall **54** is impeded. Upon collapse of the vein wall **54** around the primary-lead electrodes **34**, the polarity of the primary-lead electrodes is switched so that all primary-lead electrodes are commonly charged. The switching of polarity for the leads need not be instantaneous. The application of RF energy can be ceased, the polarity switched, and then RF energy is applied again at the switched polarity. The secondary-lead electrode **35** is then charged so that its polarity is opposite that of the primary-lead electrodes **34**. The RF field is set up between the primary-lead electrodes **34** and the secondary-lead electrode **35**.

The catheter **10** is then pulled back while energy is applied to the electrode device. As shown in FIG. **7***b*, while the catheter **10** is being pulled back, the primary-lead electrodes **34** remain in apposition with the vein wall **54** while the secondary-lead electrode **35** comes in contact with the portion of the vein wall previously collapsed by the primary-lead electrodes **34**. Accordingly, RF energy passes through the vein wall **54** between the primary-lead electrodes **34** and the secondary-lead electrode **35** and the vein wall continues to collapse around the secondary-lead electrode **35** as the catheter **10** is being retracted. As shown in FIG. **7***c*, ligation in accordance with this method results in an occlusion along a length of the vein **52**. A lengthy occlusion, as opposed to an acute occlusion, is stronger and less susceptible to recanalization.

A similar result is achieved when the catheter **10** having both primary and secondary leads is operated in a monopolar manner. In a monopolar operation, the secondary-lead electrode **35** remains neutral, while the primary leads **30** are commonly charged and act in conjunction with an independent electrical device, such as a large low-impedance return pad (not shown) placed in external contact with the body, to form a series of discrete RF fields. These RF fields are substantially evenly spaced around the circumference of the vein and travel along the axial length of the vein wall causing the vein wall to collapse around the primary-lead electrodes. Upon collapse of the vein wall, the secondary-lead electrode is charged to have the same polarity as that of the primary-lead electrodes. The electrode device is

retracted and the vein wall collapses as described in the bipolar operation.

In either bipolar or monopolar operation the application of RF energy is substantially symmetrically distributed through the vein wall, regardless of the diameter of the vein **52**. This symmetrical distribution of RF energy increases the predictability and uniformity of the shrinkage and the strength of the occlusion. Furthermore, the uniform distribution of energy allows for the application of RF energy for a short duration and thereby reduces or avoids the formation of heat-induced coagulum on the electrodes **34**. The leads, including the non-convex outer portion of the electrode, are insulated to further prevent heating of the surrounding blood.

Fluid can be delivered before and during RF heating of the vein being treated through a coaxial channel formed between the external sheath **60** and the outer sheath **12**. It is to be understood that another lumen can be formed in the catheter to deliver fluid to the treatment site. The delivered fluid displaces or exsanguinates blood from the vein so as to avoid heating and coagulation of blood. Fluid can continue to be delivered during RF treatment to prevent blood from circulating back to the treatment site. The delivery of a dielectric fluid increases the surrounding impedance so that RF energy is directed into the tissue of the vein wall.

Referring now to FIGS. **8**, **8***a*, **9***a* and **9***b*, in the operation of an alternate embodiment of the catheter **10** that may be used with a guide wire **53**. As in the previous embodiment, the catheter **10** is inserted into a hollow anatomical structure, such as a vein **52**. The guide wire **53** is advanced past the point where energy application is desired. The catheter **10** is then inserted over the guide wire **53** by way of the central lumen **48** and the guide wire tube **49** (FIG. **4**) and is advanced over the guide wire through the vein to the desired point. The guide wire **53** is typically pulled back or removed before RF energy is applied to the electrode device **24**.

The actuator **25** (FIG. **1**) is then manipulated to either retract the outer sheath **12** backward, or advance the inner sheath **28** forward to expose the leads **30** through the distal orifice **14**. The leads **30** exit the distal orifice **14** and expand radially outward relative to the axis of the alignment device **36**. The leads **30** continue to move outward until apposition with the vein wall **54** occurs. The leads **30** contact the vein along a generally circumferential band of the vein wall **54**. This outward movement of the leads occurs in a substantially symmetrical fashion. As a result, the electrodes **34** are substantially evenly spaced along the circumferential band of the vein wall **54**. Alternately, the electrodes can be spaced apart in a staggered fashion such that the electrodes do not lie along the same plane. For example, adjacent electrodes can extend different lengths from the catheter so that a smaller cross-sectional profile is achieved when the electrodes are collapsed toward one another.

When the electrodes **34** are positioned at the treatment site of the vein, the power supply **22** is activated to provide suitable RF energy to the electrodes **34** so that the catheter **10** operates in either a bipolar or monopolar manner as previously described. As shown in FIGS. **9***a* and **9***b*, the energy causes the vein wall **54** to collapse around the electrodes **34** causing the leads to substantially straighten and the electrodes to cluster around each other. The wall **54** continues to collapse until further collapse is impeded by the electrodes **34** (FIG. **9***b*). At this point the application of energy may cease. The electrodes can be configured to form a shape with a reduced profile when collapsed together. The electrodes can also be configured and insulated to continue applying RF energy after forming a reduced profile shape by the collapse of the vein wall. The catheter **10** can be pulled back to ligate the adjacent venous segment. If a temperature sensor **26** is included, the application of energy may cease prior to complete collapse if the temperature of the venous tissue rises above an acceptable level as defined by the controller **23**.

Where the catheter includes a fluid delivery lumen (not shown), fluid can be delivered before and during RF heating of the vein being treated. The fluid can displace blood from the treatment area in the vein to avoid the coagulation of blood. The fluid can be a dielectric medium. The fluid can include an anticoagulant such as heparin which can chemically discourage the coagulation of blood at the treatment site.

After completing the procedure for a selected venous section, the actuator mechanism causes the primary leads to return to the interior of the outer sheath **12**. Either the outer sheath or the inner sheath is moved to change the position of the two elements relative to one another. Once the leads **30** are within the outer sheath **12**, the catheter **10** may be moved to another venous section where the ligation process is repeated. Upon treatment of all venous sites, the catheter **10** is removed from the vasculature. The access point of the vein is then sutured closed, or local pressure is applied until bleeding is controlled.

Another embodiment of the catheter is illustrated in FIG. **10**. The inner member or sheath **28** is contained within the outer sheath **12**. The inner sheath is preferably constructed from a flexible polymer such as polyimide, polyethylene, or nylon, and can travel the entire length of the catheter. The majority of the catheter should be flexible so as to navigate the tortuous paths of the venous system. A hypotube having a flared distal end **33** and a circular cross-sectional shape is attached over the distal end of the inner sheath **28**. The hypotube is preferably no more than about two to three centimeters in length. The hypotube acts as part of the conductive secondary lead **31**. An uninsulated conductive electrode sphere **35** is slipped over the hypotube. The flared distal end of the hypotube prevents the electrode sphere from moving beyond the distal end of the hypotube. The sphere is permanently affixed to the hypotube, such as by soldering the sphere both front and back on the hypotube. The majority or the entire surface of the spherical electrode **35** remains uninsulated. The remainder of the hypotube is preferably insulated so that the sphere-shaped distal end can act as the electrode. For example, the hypotube can be covered with an insulating material such as a coating of parylene. The interior lumen of the hypotube is lined by the inner sheath **28** which is attached to the flaired distal end of the hypotube by adhesive such as epoxy.

Surrounding the secondary lead **31** and sphere-shaped electrode **35** are a plurality of primary leads **30** which preferably have a flat rectangular strip shape and can act as arms. As illustrated in FIG. **11**, the plurality of primary leads are preferably connected to common conductive rings **62**. This configuration maintains the position of the plurality of primary leads, while reducing the number of internal electrical connections. The rings **62** are attached to the inner sheath **28**. The position of the rings and the primary leads relative to the outer sheath follows that of the inner sheath. As earlier described, the hypotube of the secondary lead **31** is also attached to the inner sheath **28**. Two separate conductive rings can be used so that the polarity of different primary leads can be controlled separately. For example, adjacent primary leads can be connected to one of the two separate conductive rings so that the adjacent leads can be

switched to have either opposite polarities or the same polarity. The rings are preferable spaced closely together, but remain electrically isolated from one another along the inner sheath. Both the rings and the hypotube are coupled with the inner sheath, and the primary leads **30** that are connected to the rings move together with and secondary lead while remaining electrically isolated from one another. Epoxy or another suitable adhesive can be used to attach the rings to the inner sheath. The primary leads from the respective rings each alternate with each other along the circumference of the inner sheath. The insulation along the undefside of the leads prevents an electrical short between the rings.

The ring and primary leads are attached together to act as cantilevers where the ring forms the base and the rectangular primary leads operate as the cantilever arms. The leads **30** are connected to the ring and are formed to have an arc or bend such that the leads act as arms which tend to spring outwardly away from the catheter and toward the surrounding venous tissue. Insulation along the underside of the leads and the rings prevents unintended electrical coupling between the leads and the opposing rings. Alternately, the leads are formed straight and connected to the ring at an angle, such that the leads tend to expand or spring radially outward from the ring. The angle at which the leads are attached to the ring should be sufficient to force the primary distal ends and electrodes **34** through blood and into apposition with the vein wall. Other properties of the primary leads **30**, such as lead shape and insulation thickness, affect the push force of the lead and the degree of arc or bend must be adjusted to compensate for these factors. The rectangular cross section of the leads **30** can provide increased stability in the lateral direction while allowing the necessary bending in the radial direction. The leads **30** are less likely to bend sideways when expanded outward, and a uniform spacing between leads is more assured. Uniform spacing between the leads **30** and the distal ends promotes uniform heating around the vein by the electrodes **34**.

The distal ends of the primary leads **30** are uninsulated to act as electrodes **34** having a spoon or hemispherical shape. The leads can be stamped to produce an integral shaped electrode at the distal end of the lead. The uninsulated outer portion of the distal end electrode **34** which is to come into apposition with the wall of the anatomical structure is preferably rounded and convex. The flattened or non-convex inner portion of the distal end is insulated to minimize any unintended thermal effect, such as on the surrounding blood in a vein. The distal end electrodes **34** are configured such that when the distal ends are forced toward the inner sheath **12**, as shown in FIG. **10***a*, the distal ends combine to form a substantially spherical shape with a profile smaller than the profile for the spherical electrode **35** at the secondary distal end.

The outer sheath **12** can slide over and surround the primary and secondary leads **30, 31**. The outer sheath **12** includes an orifice which is dimensioned to have approximately the same size as the spherical electrode **35** at the secondary distal end which functions as an electrode. A close or snug fit between the electrode **35** at the secondary distal end and the orifice of the outer sheath **12** is achieved. This configuration provides an atruamatic tip for the catheter. The electrode **35** secondary distal end is preferably slightly larger than the orifice. The inner diameter of the outer sheath **12** is approximately the same as the reduced profile of the combined primary distal end electrodes **34**. The diameter of the reduced profile of the combined primary distal end electrodes **34** is preferably less than the inner diameter of the outer sheath.

A fluid port (not shown) can communicate with the interior of the outer sheath **12** so that fluid can be flushed between the outer sheath **12** and the inner sheath **28**. Alternately, a fluid port can communicate with a central lumen **48** in the hypotube which can also accept a guidewire. As previously stated, the catheter **10** can be periodically flushed with saline which can prevent the buildup of biological fluid, such as blood, within the catheter **10**. A guide wire can be introduced through the lumen **48** for use in guiding the catheter to the desired treatment site. As previously described, a fluid can be flushed or delivered though the lumen as well. If a central lumen is not desired, the lumen of the hypotube can be filled with solder.

Preferably, the primary leads **30** and the connecting rings are connected to a power source **22** such that the polarity of the leads may be switched as desired. This allows for the electrode device **24** to operate in either a bipolar or a monopolar configuration. When adjacent primary leads **30** have opposite polarity, a bipolar electrode operation is available. When the primary leads **30** are commonly charged a monopolar electrode operation is available in combination with a large return electrode pad placed in contact with the patient. When the primary leads **30** are commonly charged, and a secondary lead **31** has an opposite polarity, a bipolar electrode operation is available. More or fewer leads may be used. The number of leads can be dependent on the size or diameter of the hollow anatomical structure to be treated.

Although not shown, it is to be understood that the catheter **10** can include a temperature sensor, such as a thermocouple, mounted in place on the distal end or electrode **34** so that the sensor is substantially flush with the exposed surface of the electrode **34**. The sensor senses the temperature of the portion of the anatomical tissue that is in apposition with the exposed electrode surface. Application of the RF energy from the electrodes **34** is halted or reduced when the monitored temperature reaches or exceeds the specific temperature that was selected by the operator, such as the temperature at which anatomical tissue begins to cauterize. Other techniques such as impedance monitoring, and ultrasonic pulse echoing can be utilized in an automated system which shuts down or regulates the application of RF energy from the electrodes to the venous section when sufficient shrinkage of the vein is detected and to avoid overheating the vein.

Referring now to FIGS. **12** through **14**, in the operation of one embodiment of the catheter **10**, the catheter is inserted into a hollow anatomical structure, such as a vein. Fluoroscopy, ultrasound, an angioscope imaging technique, or another technique may be used to direct and confirm the specific placement of the catheter in the vein. The actuator is then operated to retract the outer sheath **12** to expose the leads **30, 31**. As the outer sheath no longer restrains the leads, the primary leads **30** move outward relative to the axis defined by the outer sheath, while the secondary lead **31** remains substantially linear along the axis defined by the outer sheath. The primary leads **30** continue to move outward until the distal end electrode **34** of the primary leads are placed in apposition with the vein wall **54** occurs and the outward movement of the primary leads **30** is impeded. The primary leads **30** contact the vein along a generally circumferential area of the vein wall **54**. This outward movement of the primary leads **30** occurs in a substantially symmetrical fashion so that the primary distal end electrodes **34** are substantially evenly spaced. The central-lead electrode **35** is suspended within the vein without contacting the vein wall **54**.

When the electrodes **34** are positioned at the treatment site of the vein, the power supply **22** is activated to provide

suitable RF energy. In a bipolar operation, the primary leads **30** are initially charged such that adjacent leads are oppositely charged while the secondary lead is electrically neutral. These multiple pairs of oppositely charged leads **30** form active electrode pairs to produce an RF field between them, and form a symmetrical RF field pattern along a circumferential band of the vein wall to achieve a uniform temperature distribution along the vein wall being treated.

The RF energy produces a thermal effect which causes the venous tissue to shrink, reducing the diameter of the vein. As shown in FIG. **13**, the energy causes the vein wall **54** to collapse until further collapse is impeded by the electrodes **34**. The electrodes are pressed closer together by the shrinking vein wall. The electrodes **34** are pressed together to assume a reduced profile shape which is sufficiently small so that the vein is effectively ligated. Upon collapse of the vein wall **54** around the primary-lead electrodes **34**, the polarity of the primary-lead electrodes is switched so that all of the primary-lead electrodes are commonly charged. The secondary-lead electrode **35** is then charged so that its polarity is opposite that of the primary-lead electrodes **34**. Where the primary electrodes **34** and the secondary electrode **35** are spaced sufficiently close together, when the vein wall collapses around the primary lead electrodes, the electrode at the distal end of the secondary lead can also come into contact with the a portion of the vein wall so that an RF field is created between the primary electrodes **34** and the secondary electrode **35**.

The catheter **10** is pulled back to ensure apposition between the electrodes at the distal ends of the leads and the vein wall. When the catheter **10** is being pulled back, the primary-lead electrodes **34** remain in apposition with the vein wall **54** while the secondary-lead electrode **35** comes in contact with the portion of the vein wall previously collapsed by the primary-lead electrodes **34**. RF energy passes through the venous tissue between the primary-lead electrodes **34** and the secondary-lead electrode **35**. Ligation as the catheter is being retracted produces a lengthy occlusion which is stronger and less susceptible to recanalization than an acute point occlusion.

In a monopolar operation, the secondary-lead electrode **35** remains neutral, while the primary leads **30** are commonly charged and act in conjunction with an independent electrical device, such as a large low-impedance return pad (not shown) placed in external contact with the body, to form RF fields substantially evenly spaced around the circumference of the vein. The thermal effect produced by those RF fields along the axial length of the vein wall causes the vein wall to collapse around the primary-lead electrodes. Upon collapse of the vein wall, the secondary-lead electrode is charged to have the same polarity as that of the primary-lead electrodes. The electrode device is retracted as described in the bipolar operation.

In either bipolar or monopolar operation the application of RF energy is substantially symmetrically distributed through the vein wall. As previously described, the electrodes should be spaced no more than 4 or 5 millimeters apart along the circumference of the vein, which defines the target vein diameter for a designed electrode catheter. Where the electrodes are substantially evenly spaced in a substantially symmetrical arrangement, and the spacing between the electrodes is maintained, a symmetrical distribution of RF energy increases the predictability and uniformity of the shrinkage and the strength of the occlusion.

As shown in FIG. **14**, after the electrodes **34** come into apposition with the vein wall (FIG. **12**), and before the energy is applied to ligate the vein (FIG. **13**), an external tourniquet, such as an elastic compressive wrap or an inflatable bladder with a window transparent to ultrasound, is used to compress the anatomy, such as a leg, surrounding the structure to reduce the diameter of the vein. Although the compressive force being applied by the tourniquet may effectively ligate the vein, or otherwise occlude the vein by flattening the vein, for certain veins, this compressive force will not fully occlude the vein. A fixed diameter electrode catheter in this instance would not be effective. The electrodes **34** which are expanded outward by the formed leads **30** can accommodate this situation.

The reduction in vein diameter assists in pre-shaping the vein to prepare the vein to be molded to a ligated state. The use of an external tourniquet also exsanguinates the vein and blood is forced away from the treatment site. Coagulation of blood during treatment can be avoided by this procedure. Energy is applied from the electrodes to the exsanguinated vein, and the vein is molded to a sufficiently reduced diameter to achieve ligation. The external tourniquet can remain in place to facilitate healing.

The catheter can be pulled back during the application of RF energy to ligate an extensive section of a vein. In doing so, instead of a single point where the diameter of the vein has been reduced, an extensive section of the vein has been painted by the RF energy from the catheter. Retracting the catheter in this manner produces a lengthy occlusion which is less susceptible to recanalization. The combined use of the primary and secondary electrodes can effectively produce a reduced diameter along an extensive length of the vein. The catheter can be moved while the tourniquet is compressing the vein, of after the tourniquet is removed.

Where the catheter includes a fluid delivery lumen, fluid can be delivered to the vein before RF energy is applied to the vein. The delivered fluid displaces blood from the treatment site to ensure that blood is not present at the treatment site, even after the tourniquet compresses the vein.

Where the tourniquet is an inflatable bladder with a window transparent to ultrasound, an ultrasound transducer is used to monitor the flattening or reduction of the vein diameter from the compressive force being applied by the inflating bladder. The window can be formed from polyurethane, or a stand-off of gel contained between a polyurethane pouch. A gel can be applied to the window to facilitate ultrasound imaging of the vein by the transducer. Ultrasound visualization through the window allows the operator to locate the desired venous treatment area, and to determine when the vein has been effectively ligated or occluded. Ultrasound visualization assists in monitoring any pre-shaping of the vein in preparation of being molded into a ligated state by the thermal effect produced by the RF energy from the electrodes.

After completing the procedure for a selected venous section, the actuator causes the leads **30** to return to the interior of the outer sheath **12**. Once the leads **30** are within the outer sheath **12**, the catheter **10** may be moved to another venous section where the ligation process is repeated.

The description of the component parts discussed above are for a catheter to be used in a vein ranging in size from 2 mm (0.08 in) to 10 mm (0.4 in) in diameter. It is to be understood that these dimensions do not limit the scope of the invention and are merely exemplary in nature. The dimensions of the component parts may be changed to configure a catheter **10** that may used in various-sized veins or other anatomical structures.

Although described above as positively charged, negatively charged, or as a positive conductor or negative

conductor, these terms are used for purposes of illustration only. These terms are generally meant to refer to different electrode potentials and are not meant to indicate that any particular voltage is positive or negative. Furthermore, other types of energy such as light energy from fiber optics can be used to create a thermal effect in the hollow anatomical structure undergoing treatment.

While several particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A method of applying energy to a vein to cause the vein to durably assume a reduced diameter, the method comprising the steps of:

introducing a catheter having a working end into a vein having an inner wall;

pre-shaping the vein such that the inner wall of the vein is brought toward the working end of the catheter so as to reduce the diameter of the vein;

applying energy from the working end of the catheter to the vein so as to cause the vein to durably assume a diameter at least as small as the reduced diameter achieved in the step of pre-shaping the inner wall of the vein toward the working end of the catheter;

moving the catheter along the vein during the step of applying energy.

2. The method of claim 1 wherein a lengthy occlusion is formed along the area of the vein in which the catheter is moved.

3. The method of claim 1 wherein the step of pre-shaping the vein includes the step of compressing the vein at the location of the working end of the catheter.

4. The method of claim 1 further comprising the step of delivering fluid to the vein where the working end of the catheter is located.

5. The method of claim 4 wherein the step of delivering fluid comprises the step of delivering saline to the vein.

6. The method of 4 wherein the step of delivering fluid comprises the step of delivering dielectric fluid to the vein.

7. The method of claim 4 wherein the step of delivering fluid comprises the step of delivering heparin to the vein.

8. The method of claim 1 wherein the step of applying energy includes the step of applying RF energy.

9. The method of claim 1 wherein the step of applying energy includes the step of applying electrical energy.

10. The method of claim 1 wherein the step of applying energy includes the step of applying light energy.

11. The method of claim 1 wherein the step of applying energy includes the step of applying thermal energy.

12. The method of claim 1 further comprising the step of monitoring the reduced diameter of the vein during the step of pre-shaping the vein.

13. The method of claim 1 further comprising the step of monitoring the temperature at the working end of the catheter in the vein during the step of applying energy.

14. A method of applying energy to a hollow anatomical structure to cause the hollow anatomical structure to durably assume a reduced diameter, the method comprising the steps of:

introducing a catheter having a working end into a hollow anatomical structure having an inner wall;

pre-shaping the hollow anatomical structure such that the inner wall of the hollow anatomical structure is brought toward the working end of the catheter so as to reduce the diameter of the hollow anatomical structure, wherein the working end of the catheter is in apposition with the inner wall of the hollow anatomical structure;

applying energy from the working end of the catheter to the hollow anatomical structure so as to cause the hollow anatomical structure to durably assume a diameter at least as small as the reduced diameter achieved in the step of pre-shaping;

moving the catheter along the hollow anatomical structure during the step of applying energy.

15. The method of claim 14 wherein a lengthy occlusion is formed along the area of the hollow anatomical structure in which the catheter is moved during the step of applying energy.

16. The method of claim 14 wherein the step of pre-shaping the hollow anatomical structure includes the step of compressing the hollow anatomical structure at the location of the working end of the catheter.

17. The method of claim 14 further comprising the step of delivering fluid to the hollow anatomical structure where the working end of the catheter is located.

18. The method of claim 17 wherein the step of delivering fluid comprises the step of delivering saline.

19. The method of claim 17 wherein the step of delivering fluid comprises the step of delivering dielectric fluid.

20. The method of claim 17 wherein the step of delivering fluid comprises the step of delivering heparin.

21. The method of claim 14 wherein the step of applying energy includes the step of applying RF energy.

22. The method of claim 14 wherein the step of applying energy includes the step of applying electrical energy.

23. The method of claim 14 wherein the step of applying energy includes the step of applying light energy.

24. The method of claim 14 wherein the step of applying energy includes the step of applying thermal energy.

25. The method of claim 14 further comprising the step of monitoring the reduced diameter of the hollow anatomical structure during the step of pre-shaping.

26. The method of claim 14 further comprising the step of monitoring the temperature at the working end of the catheter in the hollow anatomical structure during the step of applying energy.

27. A method of applying energy to a vein to cause the vein to durably assume a reduced diameter, the method comprising the steps of:

introducing a catheter having a working end into a vein having an inner wall;

pre-shaping the vein such that the inner wall of the vein is brought toward the working end of the catheter so as to reduce the diameter of the vein, wherein the working end of the catheter is in apposition with the inner wall of the vein;

applying energy from the working end of the catheter to the vein so as to cause the vein to durably assume a diameter at least as small as the reduced diameter achieved in the step of pre-shaping;

moving the catheter along the vein during the step of applying energy, wherein a lengthy occlusion is formed along the area of the vein in which the catheter is moved during the step of applying energy.

28. The method of claim 27 further comprising the step of delivering fluid to the vein where the working end of the catheter is located.

29. The method of claim 28 wherein the step of delivering fluid comprises the step of delivering saline to the vein.

30. The method of claim 28 wherein the step of delivering fluid comprises the step of delivering dielectric fluid to the vein.

31. The method of claim 28 wherein the step of delivering fluid comprises the step of delivering heparin to the vein.

32. The method of claim 27 wherein the step of applying energy includes the step of applying RF energy.

33. The method of claim 27 wherein the step of applying energy includes the step of applying electrical energy.

34. The method of claim 27 wherein the step of applying energy includes the step of applying light energy.

35. The method of claim 27 wherein the step of applying energy includes the step of applying thermal energy.

36. The method of claim 27 further comprising the step of monitoring the reduced diameter of the vein during the step of pre-shaping.

37. The method of claim 27 wherein the step of pre-shaping the vein includes the step of compressing the vein at the location of the working end of the catheter.

38. The method of claim 27 further comprising the step of monitoring the temperature at the working end of the catheter in the vein during the step of applying energy.

39. A method of applying energy to a vein to cause the vein to durably assume a reduced diameter, the method comprising the steps of:

introducing a catheter having a working end into a vein having an inner wall;

pre-shaping the vein such that the inner wall of the vein is brought toward the working end of the catheter so as to reduce the diameter of the vein;

applying energy from the working end of the catheter to the vein so as to cause the vein to durably assume a diameter at least as small as the reduced diameter achieved in the step of pre-shaping;

moving the catheter to a new location along the vein after the step of applying energy;

applying energy from the working end of the catheter to the new location along the vein so as to cause the vein to durably assume a diameter at least as small as the reduced diameter achieved in the step of pre-shaping.

40. The method of claim 39 wherein a lengthy occlusion is formed along the area of the vein in which the catheter is moved.

41. The method of claim 39 wherein the step of pre-shaping the vein includes the step of compressing the vein at the location of the working end of the catheter.

42. The method of claim 39 further comprising the step of delivering fluid to the vein where the working end of the catheter is located.

43. The method of claim 42 wherein the step of delivering fluid comprises the step of delivering saline to the vein.

44. The method of claim 42 wherein the step of delivering fluid comprises the step of delivering dielectric fluid to the vein.

45. The method of claim 42 wherein the step of delivering fluid comprises the step of delivering heparin to the vein.

46. The method of claim 39 wherein the step of applying energy includes the step of applying RF energy.

47. The method of claim 39 wherein the step of applying energy includes the step of applying electrical energy.

48. The method of claim 39 the step of applying energy includes the step of applying light energy.

49. The method of claim 39 wherein the step of applying energy includes the step of applying thermal energy.

50. The method of claim 39 further comprising the step of monitoring the reduced diameter of the vein during the step of pre-shaping.

51. The method of claim 39 further comprising the step of monitoring the temperature at the working end of the catheter in the vein during the steps of applying energy.

52. A method of applying energy to a hollow anatomical structure to cause the hollow anatomical structure to durably assume a reduced diameter, the method comprising the steps of:

introducing a catheter having a working end into a hollow anatomical structure having an inner wall;

pre-shaping the hollow anatomical structure such that the inner wall of the hollow anatomical structure is brought toward the working end of the catheter so as to reduce the diameter of the hollow anatomical structure, wherein the working end of the catheter is in apposition with the inner wall of the hollow anatomical structure;

applying energy from the working end of the catheter to the hollow anatomical structure so as to cause the hollow anatomical structure to durably assume a diameter at least as small as the reduced diameter achieved in the step of pre-shaping;

moving the catheter to a new location along the hollow anatomical structure after the step of applying energy;

applying energy from the working end of the catheter to the new location along the hollow anatomical structure so as to cause the hollow anatomical structure to durably assume a diameter at least as small as the reduced diameter achieved in the step of pre-shaping.

53. The method of claim 52 wherein a lengthy occlusion is formed along the area of the hollow anatomical structure in which the catheter is moved.

54. The method of claim 52 wherein the step of pre-shaping the hollow anatomical structure includes the step of compressing the hollow anatomical structure at the location of the working end of the catheter.

55. The method of claim 52 further comprising the step of delivering fluid to the hollow anatomical structure where the working end of the catheter is located.

56. The method of claim 55 wherein the step of delivering fluid comprises the step of delivering saline.

57. The method of claim 55 wherein the step of delivering fluid comprises the step of delivering dielectric fluid.

58. The method of claim 55 wherein the step of delivering fluid comprises the step of delivering heparin.

59. The method of claim 52 wherein the step of applying energy includes the step of applying RF energy.

60. The method of claim 52 wherein the step of applying energy includes the step of applying electrical energy.

61. The method of claim 52 wherein the step of applying energy includes the step of applying light energy.

62. The method of claim 52 wherein the step of applying energy includes the step of applying thermal energy.

63. The method of claim 52 further comprising the step of monitoring the reduced diameter of the hollow anatomical structure during the step of pre-shaping.

64. The method of claim 52 further comprising the step of monitoring the temperature at the working end of the catheter in the hollow anatomical structure during the steps of applying energy.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

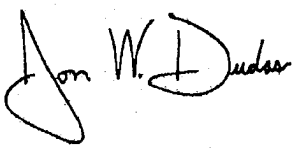
PATENT NO. : 6,769,433 B2
DATED : August 3, 2004
INVENTOR(S) : Farley et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 21,
Line 62, insert -- wherein -- after "claim 39".

Signed and Sealed this

Twenty-first Day of June, 2005



JON W. DUDAS
Director of the United States Patent and Trademark Office

EXHIBIT 3

US006258084B1

(12) **United States Patent**
Goldman et al.

(10) **Patent No.: US 6,258,084 B1**
(45) **Date of Patent: Jul. 10, 2001**

(54) **METHOD FOR APPLYING ENERGY TO BIOLOGICAL TISSUE INCLUDING THE USE OF TUMESCENT TISSUE COMPRESSION**

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(73) Assignee: **Vnus Medical Technologies, Inc.**, Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/267,127**

(22) Filed: **Mar. 10, 1999**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/927,251, filed on Sep. 11, 1997, and a continuation-in-part of application No. 09/138,472, filed on Aug. 21, 1998.

(51) **Int. Cl.**[7] **A61B 18/04**
(52) **U.S. Cl.** **606/32**; 128/898
(58) **Field of Search** 606/27–29, 31, 606/32, 34, 41, 42; 607/1, 2, 96, 98, 100–102, 104–106; 604/49; 128/898

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Assistant Examiner—R. Kearney
(74) *Attorney, Agent, or Firm*—Fulwider Patton Lee & Utecht, LLP

(57) **ABSTRACT**

An electrode catheter is introduced into a hollow anatomical structure, such as a vein, and is positioned at a treatment site within the structure. Tumescent fluid is injected into the tissue surrounding the treatment site to produce tumescence of the surrounding tissue which then compresses the vein. The solution may include an anesthetic, and may further include a vasoconstrictive drug that shrinks blood vessels. The tumescent swelling in the surrounding tissue causes the hollow anatomical structure to become compressed, thereby exsanguinating the treatment site. Energy is applied by an electrode catheter in apposition with the vein wall to create a heating effect. The heating effect causes the hollow anatomical structure to become molded and durably assume the compressed dimensions caused by the tumescent technique. The electrode catheter can be moved within the structure so as to apply energy to a large section of the hollow anatomic structure. In a further aspect, the location of the electrodes is determined by impedance monitoring. Also, temperature sensors at the treatment site are averaged to determine the site temperature.

39 Claims, 6 Drawing Sheets

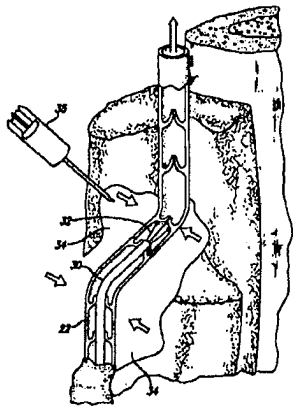

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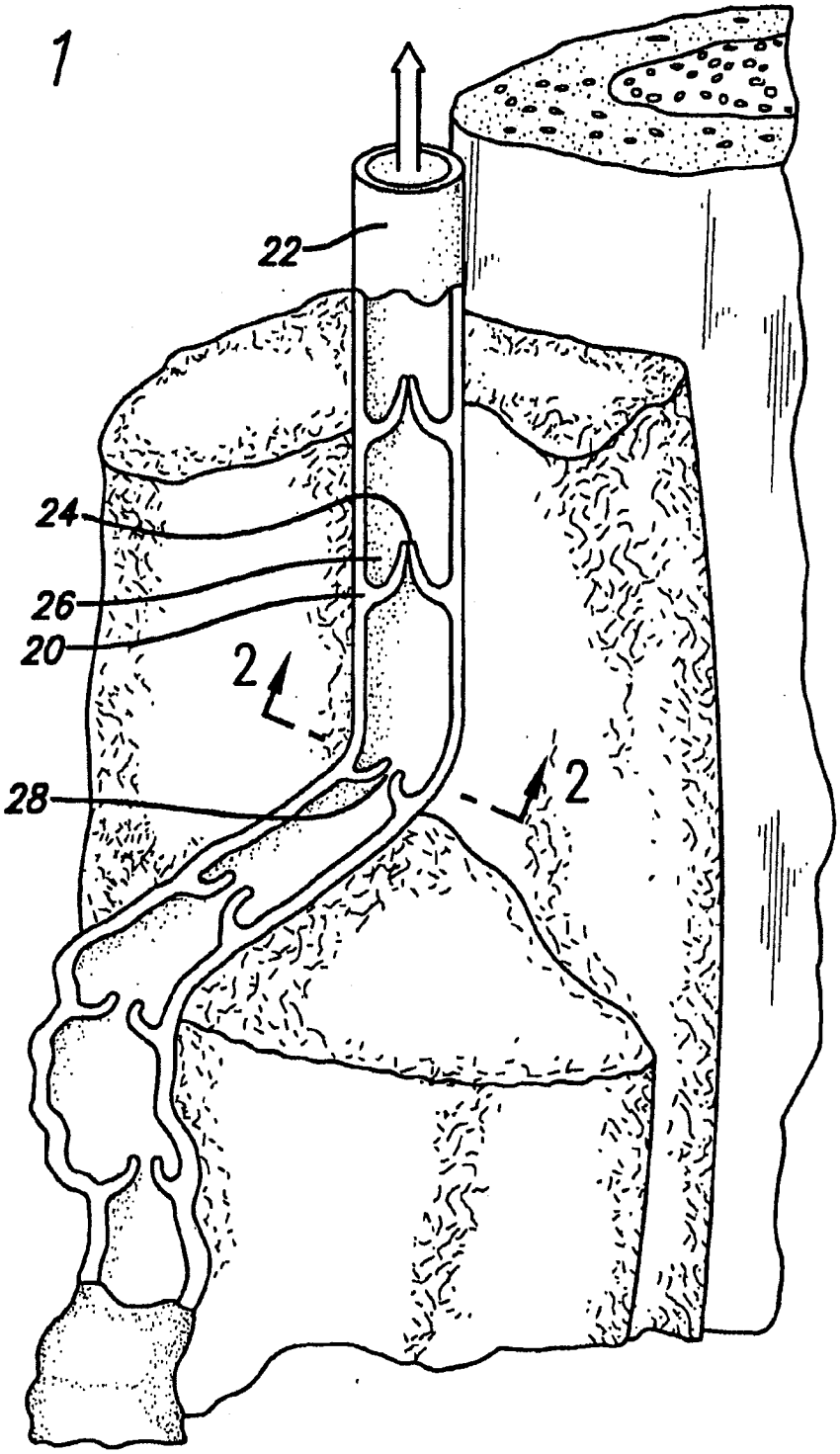
FIG. 1



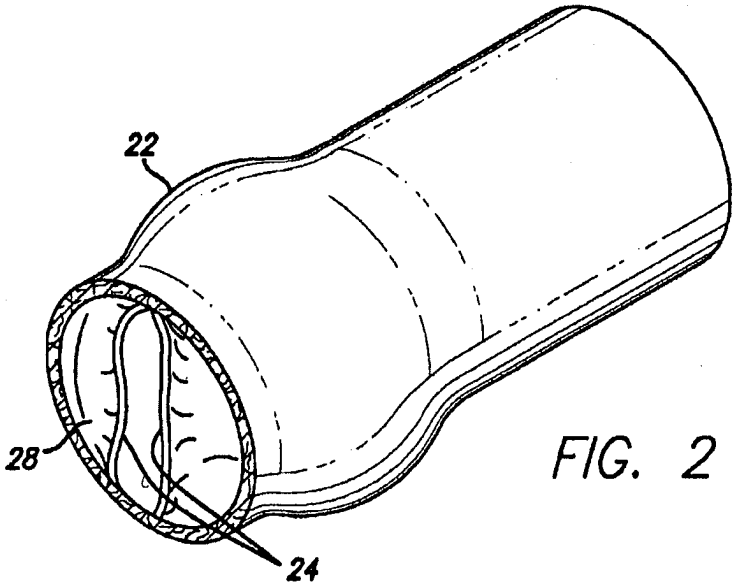


FIG. 2

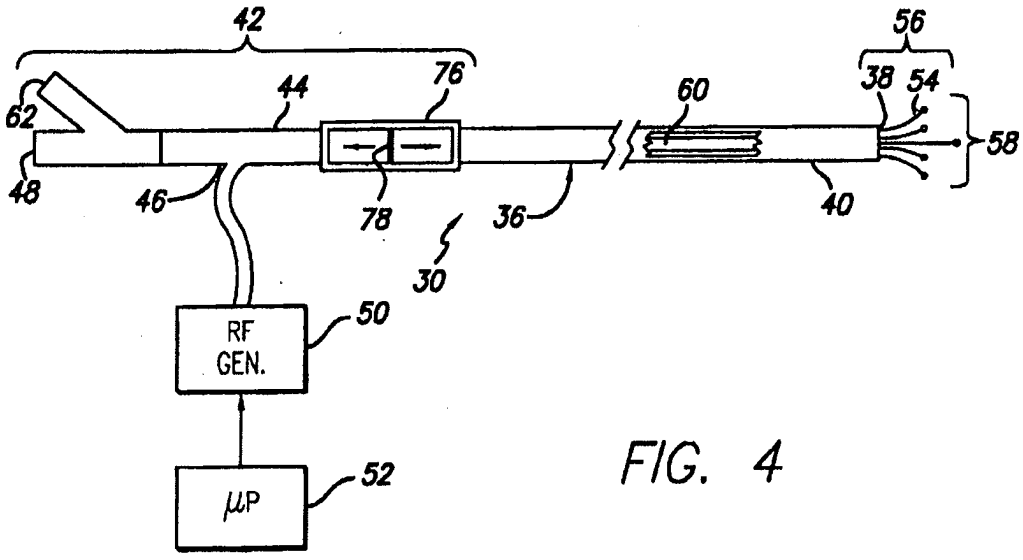
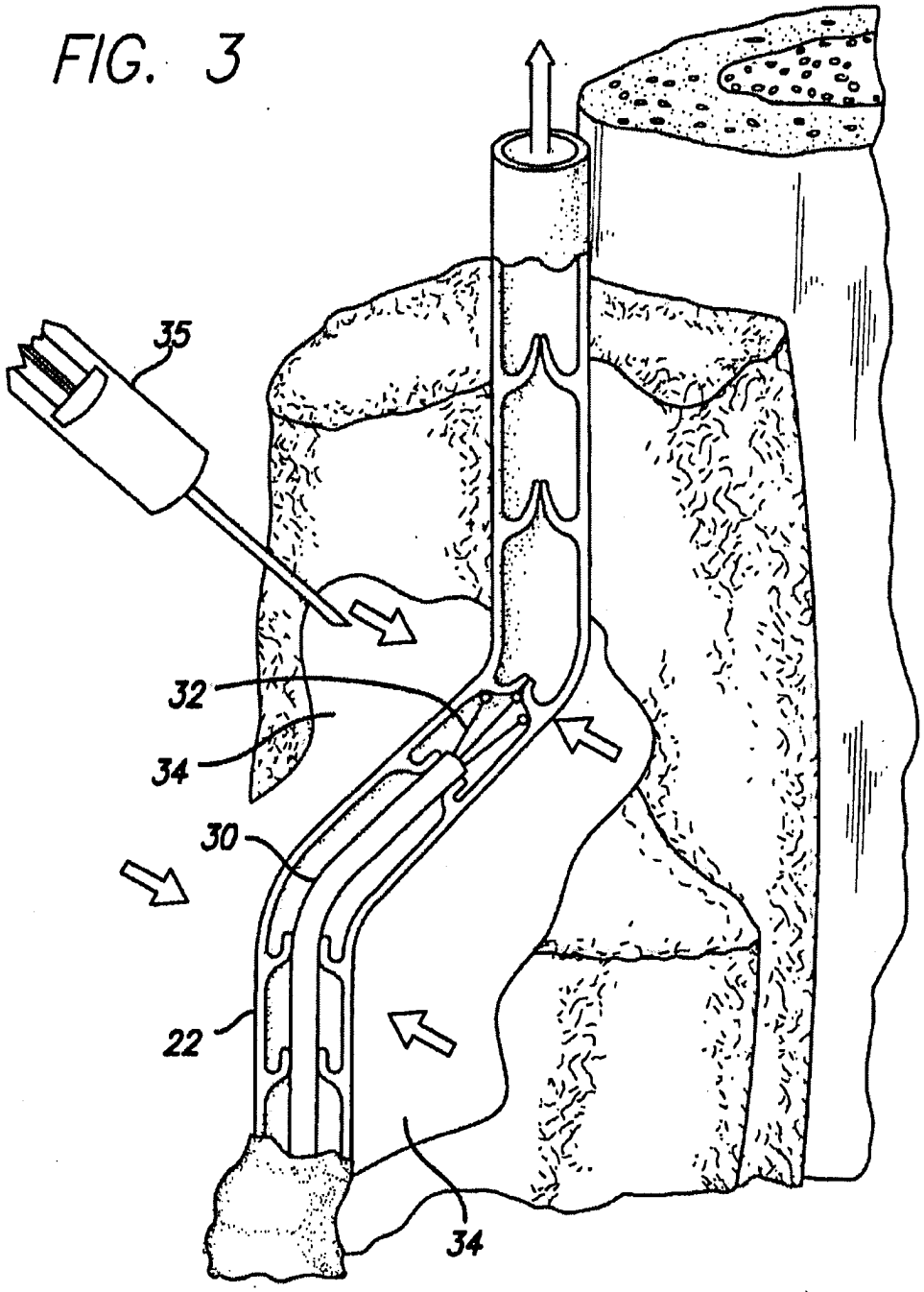


FIG. 4

FIG. 3



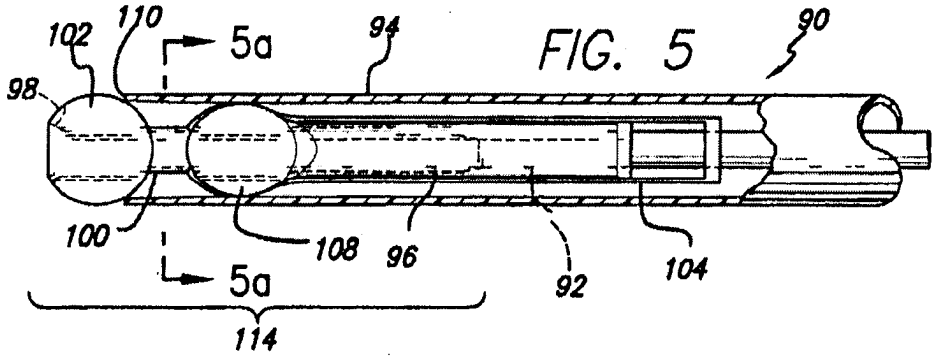


FIG. 5

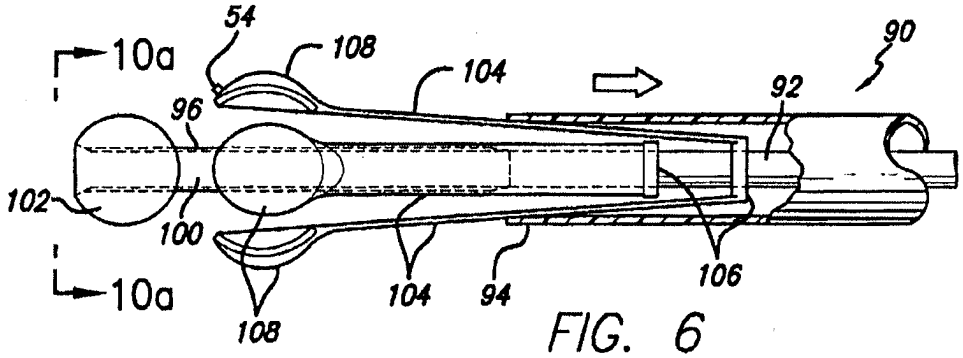


FIG. 6

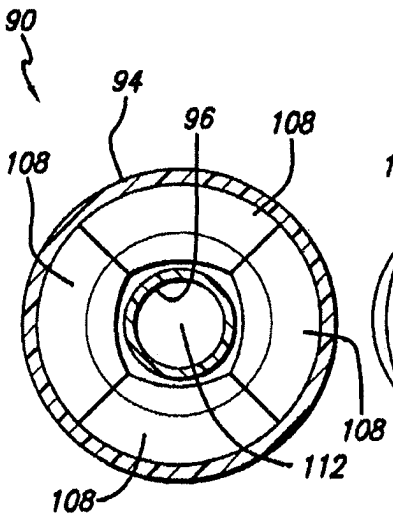


FIG. 5a

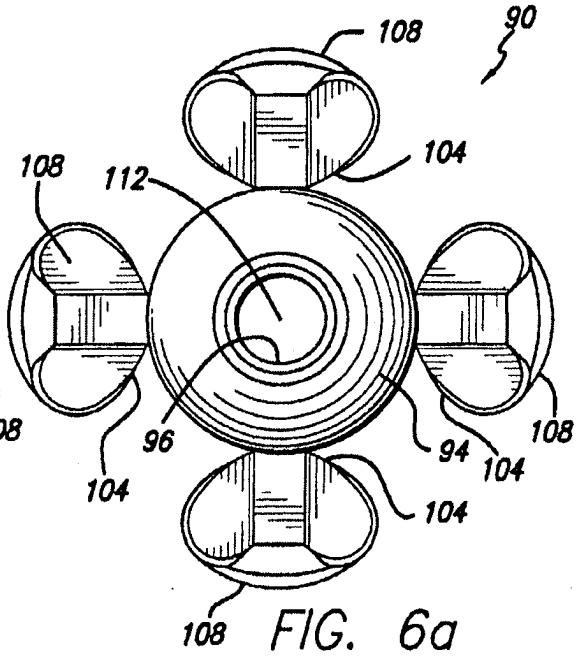


FIG. 6a

FIG. 7

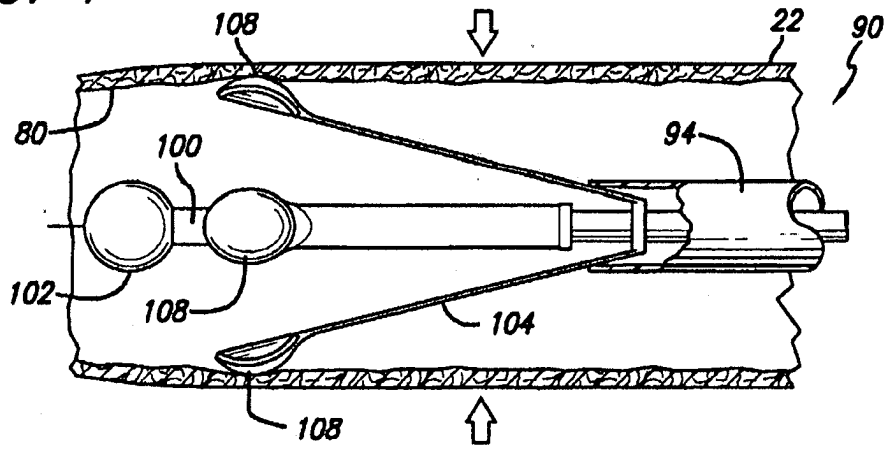


FIG. 8

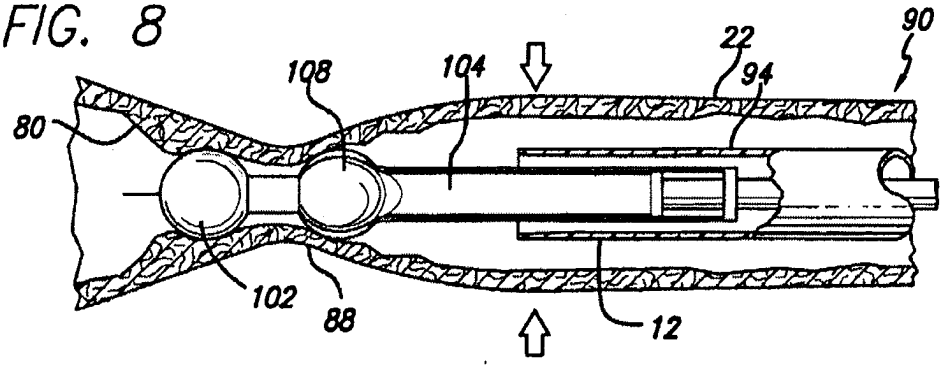
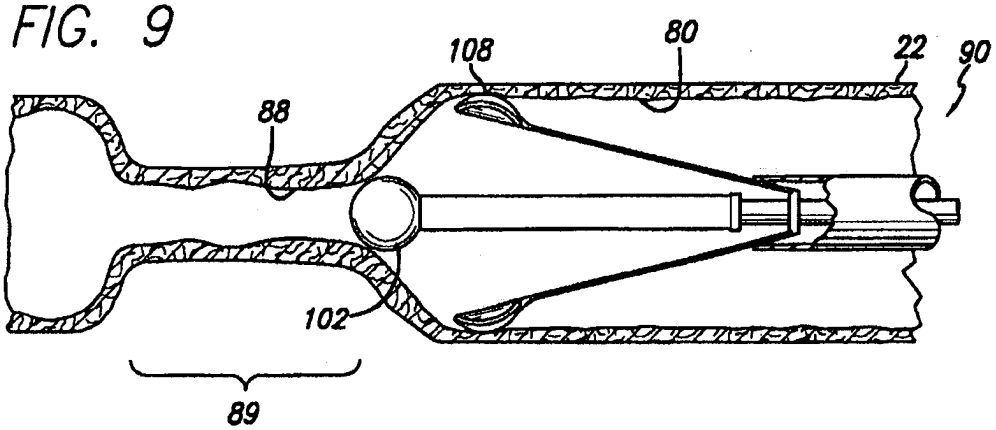


FIG. 9



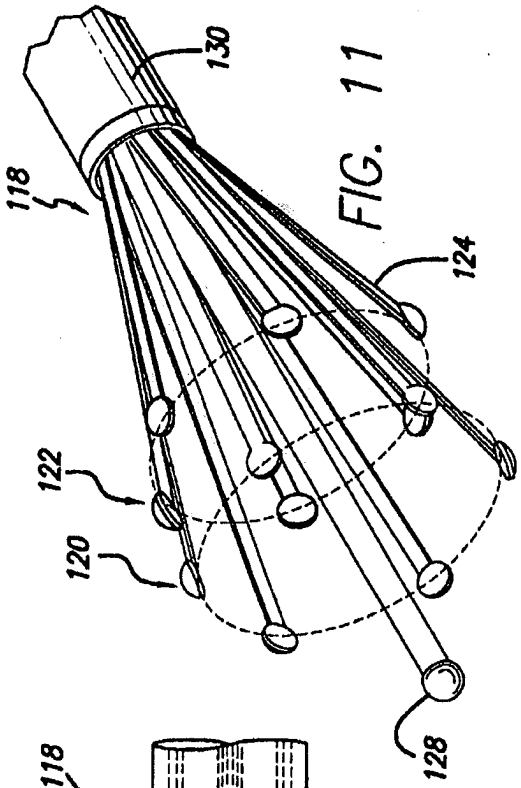


FIG. 11

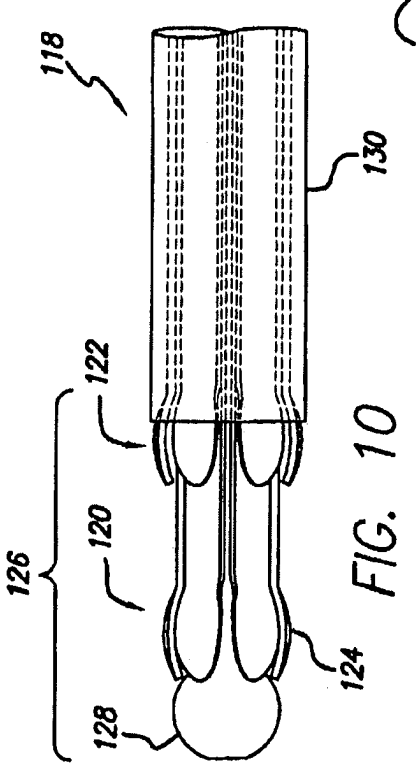


FIG. 10

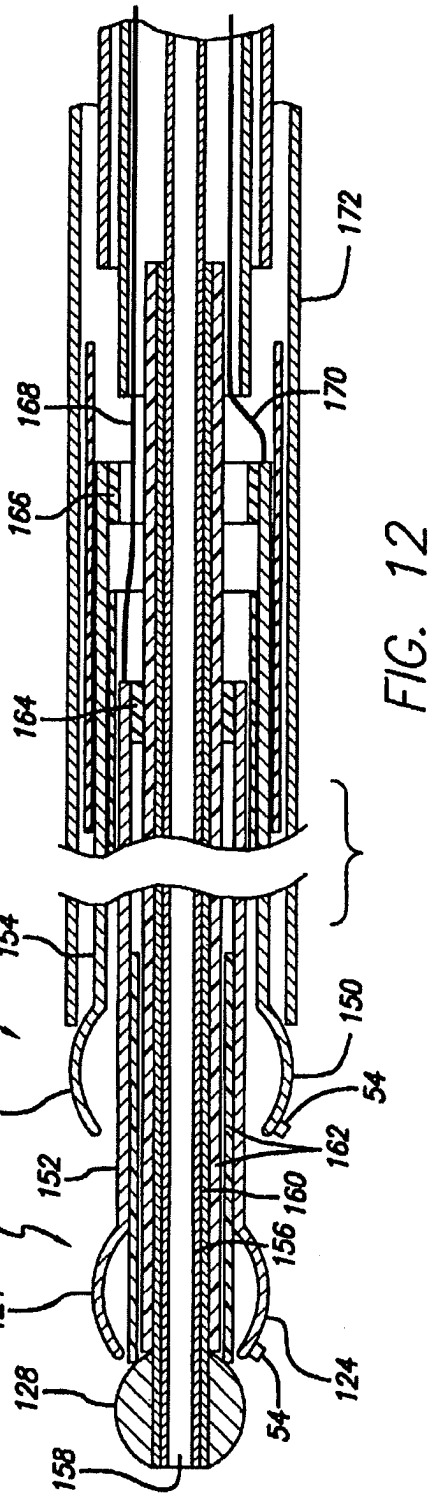


FIG. 12

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METHOD FOR APPLYING ENERGY TO BIOLOGICAL TISSUE INCLUDING THE USE OF TUMESCENT TISSUE COMPRESSION

This is a continuation-in-part of co-pending application Ser. No. 08/927,251 filed on Sep. 11, 1997 and co-pending application Ser. No. 09/138,472 filed on Aug. 21, 1998.

BACKGROUND

The invention relates generally to a method and apparatus for applying energy to shrink a hollow anatomical structure, such as a fallopian tube or a vein, including but not limited to, superficial and perforator veins, hemorrhoids, and esophageal varices. In some particular aspects, the invention relates to a method for compressing an anatomical structure prior to the application of energy and apparatus including an electrode device having multiple leads for applying energy to the compressed structure to cause it to durably assume its compressed form.

The human venous system of the lower limbs consists essentially of the superficial venous system and the deep venous system with perforating veins connecting the two systems. The superficial system includes the long or great saphenous vein and the short saphenous vein. The deep venous system includes the anterior and posterior tibial veins which unite to form the popliteal vein, which in turn becomes the femoral vein when joined by the short saphenous vein.

The venous system contains numerous one-way valves for directing blood flow back to the heart such as those valves **20** located in the vein **22** shown in FIG. **1**. The arrow leading out the top of the vein represents the antegrade flow of blood back to the heart. Venous valves are usually bicuspid valves, with each cusp **24** forming a sack or reservoir **26** for blood which, under retrograde blood pressure, forces the free surfaces of the cusps together to prevent retrograde flow of the blood and allows only antegrade blood flow to the heart. Competent venous valves prevent retrograde flow as blood is pushed forward through the vein lumen and back to the heart. When an incompetent valve **28** is in the flow path, the valve is unable to close because the cusps do not form a proper seal and retrograde flow of the blood cannot be stopped. When a venous valve fails, increased strain and pressure occur within the lower venous sections and overlying tissues, sometimes leading to additional valvular failure. Incompetent valves may result from the stretching of dilated veins. As the valves fail, increased pressure is imposed on the lower veins and the lower valves of the vein, which in turn exacerbates the failure of these lower valves. A cross-sectional perspective view of a dilated vein with an incompetent valve **28** taken along lines **2**—**2** of FIG. **1** is illustrated in FIG. **2**. The valve cusps **24** can experience some separation at the commissure due to the thinning and stretching of the vein wall at the cusps. Two venous conditions which often result from valve failure are varicose veins and more symptomatic chronic venous insufficiency.

The varicose vein condition includes dilation and tortuosity of the superficial veins of the lower limbs, resulting in unsightly discoloration, pain, swelling, and possibly ulceration. Varicose veins often involve incompetence of one or more venous valves, which allow reflux of blood within the superficial system. This can also worsen deep venous reflux and perforator reflux. Current treatments of vein insufficiency include surgical procedures such as vein stripping, ligation, and occasionally, vein-segment transplant.

Chronic venous insufficiency involves an aggravated condition of varicose veins which may be caused by degenerative weakness in the vein valve segment, or by hydrodynamic forces acting on the tissues of the body, such as the legs, ankles, and feet. As the valves in the veins fail, the hydrostatic pressure increases on the next venous valves down, causing those veins to dilate. As this continues, more venous valves will eventually fail. As they fail, the effective height of the column of blood above the feet and ankles grows, and the weight and hydrostatic pressure exerted on the tissues of the ankle and foot increases. When the weight of that column reaches a critical point as a result of the valve failures, ulcerations of the ankle begin to form, which start deep and eventually come to the surface. These ulcerations do not heal easily because of poor venous circulation due to valvular incompetence in the deep venous system and other vein systems.

Other related venous conditions include dilated hemorrhoids and esophageal varices. Pressure and dilation of the hemorrhoid venous plexus may cause internal hemorrhoids to dilate and/or prolapse and be forced through the anal opening. If a hemorrhoid remains prolapsed, considerable discomfort, including itching and bleeding, may result. The venous return from these prolapsed hemorrhoids becomes obstructed by the anal sphincters, which gives rise to a strangulated hemorrhoid. Thromboses result where the blood within the prolapsed vein becomes clotted. This extremely painful condition can cause edema and inflammation.

Varicose veins called esophageal varices can form in the venous system with submucosa of the lower esophagus, and bleeding can occur from the dilated veins. Bleeding or hemorrhaging may result from esophageal varices, which can be difficult to stop and, if untreated, could develop into a life threatening condition. Such varices erode easily, and lead to a massive gastrointestinal hemorrhage.

Ligation of a fallopian tube (tubal ligation) for sterilization or other purposes is typically performed by laparoscopy. A doctor severs the fallopian tube or tubes and ties the ends. External cauterization or clamps may also be used. General or regional anesthetic must be used. All of the above are performed from outside the fallopian tube.

Hemorrhoids and esophageal varices may be alleviated by intra-luminal ligation. As used herein, "ligation" or "intra-luminal ligation" comprises the occlusion, collapse, or closure of a lumen or hollow anatomical structure by the application of energy from within the lumen or structure. As used herein, "ligation" or "intra-luminal ligation" includes electro-ligation. In the case of fallopian tube ligation, it would be desirable to perform the ligation from within the fallopian tube itself (intra-fallopian tube) to avoid the trauma associated with external methods.

Ligation involves the cauterization or coagulation of a lumen using energy, such as that applied through an electrode device. An electrode device is introduced into the lumen and positioned so that it contacts the lumen wall. Once properly positioned, RF energy is applied to the wall by the electrode device thereby causing the wall to shrink in cross-sectional diameter. In the case of a vein, a reduction in cross-sectional diameter of the vein, as for example from 5 mm (0.2 in) to 1 mm (0.04 in), significantly reduces the flow of blood through a lumen and results in an effective occlusion. Although not required for effective occlusion or ligation, the vein wall may completely collapse thereby resulting in a full-lumen obstruction that blocks the flow of blood through the vein. Likewise, a fallopian tube may collapse sufficiently to effect a sterilization of the patient.

One apparatus for performing ligation includes a tubular shaft having an electrode device attached at the distal tip.

Running through the shaft, from the distal end to the proximal end, are electrical leads. At the proximal end of the shaft, the leads terminate at an electrical connector, while at the distal end of the shaft the leads are connected to the electrode device. The electrical connector provides the interface between the leads and a power source, typically an RF generator. The RF generator operates under the guidance of a control device, usually a microprocessor.

The ligation apparatus may be operated in either a monopolar or bipolar configuration. In the monopolar configuration, the electrode device consists of an electrode that is either positively or negatively charged. A return path for the current passing through the electrode is provided externally from the body, as for example by placing the patient in physical contact with a large low-impedance pad. The current flows between the ligation device and low impedance pad through the patient. In a bipolar configuration, the electrode device consists of a pair of electrodes having different potentials (such as a pair of oppositely-charged electrodes) of approximately equal size, separated from each other, such as by a dielectric material or by a spatial relationship. Accordingly, in the bipolar mode, the return path for current is provided by an electrode or electrodes of the electrode device itself. The current flows from one electrode, through the tissue, and returns by way of the another electrode.

To protect against tissue damage, i.e., charring, due to cauterization caused by overheating, a temperature sensing device is typically attached to the electrode device, although it may be located elsewhere. The temperature sensing device may be a thermocouple that monitors the temperature of the venous tissue. The thermocouple interfaces with the RF generator and the controller through the shaft and provides electrical signals to the controller which monitors the temperature and adjusts the energy applied to the tissue through the electrode device accordingly.

The overall effectiveness of a ligation apparatus is largely dependent on the electrode device contained within the apparatus. Monopolar and bipolar electrode devices that comprise solid devices having a fixed shape and size can limit the effectiveness of the ligating apparatus for several reasons. Firstly, a fixed-size electrode device typically contacts the vein wall at only one point or a limited arc on the circumference or inner diameter of the vein wall. As a result, the application of RF energy is highly concentrated within the contacting venous tissue, while the flow of RF current through the remainder of the venous tissue is disproportionately weak. Accordingly, the regions of the vein wall near the area of contact collapse at a faster rate than other regions of the vein wall, resulting in non-uniform shrinkage of the vein lumen. Furthermore, the overall strength of the occlusion may be inadequate and the lumen may eventually reopen. To avoid an inadequate occlusion, RF energy must be applied for an extended period of time so that the current flows through the tissue, including through the tissue not in contact with the electrode, generating thermal energy and causing the tissue to shrink sufficiently. Extended applications of energy have a greater possibility of increasing the temperature of the blood to an unacceptable level and may result in a significant amount of heat-induced coagulum forming on the electrode and in the vein which is not desirable. Furthermore, it is possible for the undesirable coagulum to form when utilizing an expandable electrode as well. This problem can be prevented by exsanguination of the vein prior to the treatment, as well as through the use of temperature-regulated power delivery. As used herein, "exsanguination" comprises the removal of all or some significant portion of blood in a particular area.

Secondly, the effectiveness of a ligating apparatus having a fixed-size electrode device is limited to certain sized veins. An attempt to ligate a vein having a diameter that is substantially greater than the fixed-size electrode device can result in not only non-uniform heating of the vein wall as just described, but also insufficient shrinkage of the vein diameter. The greater the diameter of the vein relative to the diameter of the electrode device, the weaker the energy applied to the vein wall at points distant from the point of electrode contact. Also, larger diameter veins must shrink a larger percentage for effective occlusion to occur. Accordingly, the vein wall is likely to not completely collapse prior to the venous tissue becoming over-cauterized at the point of electrode contact. While coagulation as such may initially occlude the vein, such occlusion may only be temporary in that the coagulated blood may eventually dissolve recanalizing the vein. One solution for this inadequacy is an apparatus having interchangeable electrode devices with various diameters. Another solution is to have a set of catheters having different sizes so that one with the correct size for the diameter of the target vein will be at hand when needed. Such solutions, however, are both economically inefficient and can be tedious to use. It is desirable to use a single catheter device that is usable with a large range of sizes of lumina.

A technique of reducing the diameter of the lumen of a vein at least close to the final desired diameter before applying energy to the vein has been found to aid in the efficiency of these types of procedures. The pre-reduction in vein diameter assists in pre-shaping the vein to be molded into a ligated state. The compression also exsanguinates the vein and forces blood away from the treatment site, thus preventing coagulation. One valuable technique employed is that of compressing the vein contained within a limb by applying external hydraulic pressure, via a pressure tourniquet, to the limb. Unfortunately there are some areas of the body to which a pressure tourniquet cannot be applied, such as the sapheno-femoral junction, which is above the thigh proximate the groin area. Furthermore, there are sites where a pressure tourniquet may be ineffective such as: the popliteal junction and other areas around the knee; and the ankle area (typically the posterior arch vein and some of the lower cockett perforators).

There exists a technique referred to as tumescent anesthesia that has been used in connection with liposuction procedures. The word "tumescent" means swollen or firm. This technique is accomplished by subcutaneously delivering into target fatty tissue a large volume of saline solution containing diluted Lidocaine and Epinephrine (adrenaline), a vasoconstrictive drug. The injected area then becomes locally anesthetized, and the adrenaline temporarily constricts the capillaries and other blood vessels. The tumescence-inducing fluid, or "tumescent fluid" is injected under pressure which causes the target fatty tissue to become swollen and firm. The tumescent fluid is typically pumped into the pocket of fat in order to numb the area, loosen the fat, and constrict the blood vessels to minimize bleeding or bruising in a liposuction procedure. The anesthetic and other agents in the tumescent solution should be allowed sufficient time to diffuse and take full effect throughout the target tissue. After surgery, patients may leave without assistance, and often return to their regular routine within several days. With the tumescent technique, postoperative discomfort is significantly reduced. The local anesthesia often remains in the treated tissue for 16 hours after surgery. Employing a technique of utilizing tumescent anesthesia in conjunction with ligation or radial lumen shrinkage less than ligation may provide benefits.

Although described above in terms of a vein, the concepts are generally applicable to other hollow anatomical structures in the body as well. The above description has been generally confined to veins in consideration of avoiding unnecessary repetition.

Hence those skilled in the art have recognized a need for an improved method and apparatus that can be used on areas of the body to shrink and ligate hollow anatomical structures. A need has also been recognized for an improved method and apparatus to pre-compress and exsanguinate a hollow anatomical structure while providing anesthetic and insulation benefits during the radial shrinkage of the hollow anatomical structure. The invention fulfills these needs and others.

SUMMARY OF THE INVENTION

The present invention is directed to a method and apparatus for applying energy to a hollow anatomical structure such as a vein, to shrink the structure. In a more detailed aspect, the invention is directed to pre-compressing and exsanguinating a hollow anatomical structure while providing anesthetic and insulation benefits during a procedure of shrinking the hollow anatomical structure.

In another aspect of the present invention, a method comprises providing fluid to tissue surrounding a hollow anatomical structure to induce tumescence of the tissue and consequent compression of the hollow anatomical structure during a procedure of applying energy to the hollow anatomical structure from within the structure. In a more detailed aspect, the method comprises introducing into the hollow anatomical structure a catheter having a working end and at least one electrode at the working end; placing the electrode into contact with the inner wall of the pre-compressed hollow anatomical structure and applying energy to the hollow anatomical structure at the treatment site via the electrode until the hollow anatomical structure durably assumes dimensions less than or equal to the pre-compressed dimensions caused by the injection of the solution into the tissue.

In another aspect in accordance with the invention, tumescent fluid is injected in the tissue surrounding the hollow anatomical structure along a selected length of the hollow anatomical structure. The electrode is then moved along a site within the selected length while continuously applying energy to result in a lengthy occlusion. In another approach, after an initial application of energy to one site internal to the hollow anatomical structure within the selected length, the electrode is moved down a given length of the hollow anatomical structure and energy is applied at that adjacent site. For the site where energy is applied, the hollow anatomical structure durably assumes dimensions less than or equal to the pre-compressed dimensions caused by the injection of the solution into the tissue.

In a more detailed aspect, tumescent anesthesia fluid is injected or otherwise provided to tissue contiguous with a vein to compress the vein to about a desired final diameter. A catheter having an energy application device, such as expandable electrodes, is introduced internal to the vein at a site within the compressed portion of the vein and energy is applied to the internal vein wall by the application device. Sufficient energy is applied to cause the vein to durably assume the compressed diameter such that when the effects of the tumescent anesthesia fluid are dissipated, the vein retains the compressed diameter.

Alternate means to prevent coagulum formation include fluid displacement of blood at the treatment site, or exsanguination by inducing self-constriction of the vessel. In the latter, self-constriction includes, but is not limited to, intraluminal delivery of a vasoconstrictive drug. Self-constriction also aids in pre-shaping the vein for ligation, as discussed previously. If the fluid delivered to the site is a sclerosant, the ligation effects would be further enhanced.

In further aspects, energy is applied to effectively occlude the treatment site. Further, the energy application device is moved along the treatment site while performing the step of applying energy so as to result in a lengthy occlusion of the treatment site. The treatment site may collapse around the energy application device as it is being moved. In yet further detail, fluid is delivered from within the hollow structure to the treatment site. This fluid may be used to exsanguinate the treatment site. Such fluid may be from the following group: saline; a vasoconstrictive agent; a sclerosing agent; a high impedance fluid; and heparin.

In another aspect, temperatures are sensed at two separate locations on the energy application device, and the temperature signals are averaged to determine the temperature at the site. In further detailed aspects, electrical energy is applied to the inner wall of the treatment site with an electrode, the electrode being in apposition with the inner wall. With the electrode being in apposition with the inner wall, the method further comprises the steps of applying electrical energy with the electrode to effectively occlude the treatment site at the electrode, and moving the electrode along the treatment site while maintaining the electrode in apposition with the vein wall while performing the step of applying energy to effectively occlude the treatment site so as to result in a lengthy effective occlusion of the treatment site. Sufficient energy is applied to collapse the hollow anatomical structure around the energy application device as it is being moved along the treatment site to result in a lengthy effective occlusion of the treatment site.

In yet a further aspect, apposition of the energy application device with the inner wall of the hollow anatomical structure is determined by monitoring the impedance experienced by the energy application device.

These and other aspects and advantages of the present invention will become apparent from the following more detailed description, when taken in conjunction with the accompanying drawings which illustrate, by way of example, embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a cross-sectional view of a vein having competent valves and having a dilated section with incompetent venous valves in a lower limb which are to be treated in accordance with the present invention;

FIG. 2 shows a representative view of a venous section with an incompetent valve from FIG. 1 taken along lines 2—2 which is to be treated in accordance with the present invention;

FIG. 3 is a cross-sectional view of the vein of FIG. 1 after the vein has been compressed, although not to full occlusion, by the injection of a tumescent anesthesia fluid in tissue surrounding the vein showing a catheter including an expandable electrode device prior to the application of energy to the vein;

FIG. 4 is a diagram of an energy application system that may be used in conjunction with the method of the present invention, depicting a partial cutaway view of the first embodiment of the catheter showing both the working end and the connecting end with an RF generator and a microprocessor connected at the connection end;

FIG. **5** is a cross-sectional view of the working end of an embodiment of a catheter in accordance with the invention depicting the electrodes in a fully retracted position;

FIG. **5***a* is an end view of the working end of the embodiment of the catheter taken along line **5***a*—**5***a* of FIG. **5**;

FIG. **6** is a cross-sectional view of the working end of the embodiment of the catheter of FIGS. **5** and **5***a* depicting the electrodes in a fully expanded position;

FIG. **6***a* is an end view of the working end of the embodiment of the catheter taken along line **6***a*—**6***a* of FIG. **6**;

FIG. **7** is a cross-sectional view of a vein after the vein has been compressed, although not to full occlusion, by tumescent anesthesia fluid, the vein containing the catheter of FIG. **5** with the electrodes in apposition with the vein;

FIG. **8** is a cross-sectional view of the compressed vein containing the catheter of FIG. **5** where the vein is being ligated by the application of energy from the electrodes;

FIG. **9** is a partial cross-sectional view of the vein wall of FIG. **8** showing a lengthy effective occlusion made by moving the electrodes along the treatment site of the vein while maintaining the electrodes in apposition and continuing to apply energy to the vein wall.

FIG. **10** is a side view of an embodiment of an electrode catheter having two pluralities of longitudinally-separated expandable electrodes in a retracted condition;

FIG. **11** is a side view of the embodiment of the electrode catheter of FIG. **10** with both pluralities of the electrodes in expanded configurations; and

FIG. **12** is a partial cross-sectional view of the embodiment of an electrode catheter of FIGS. **10** and **11**.

DETAILED DESCRIPTION OF THE EMBODIMENTS

As shown in the exemplary drawings, the invention is directed toward the intravenous treatment of veins using a catheter to deliver at least one electrode to a venous treatment site. As used herein, like reference numerals will designate similar elements in the various embodiments of the present invention to be discussed. In addition, unless otherwise noted, the term "working end" will refer to the direction toward the treatment site in the patient, and the term "connecting end" will refer to the direction away from the treatment site in the patient. The invention will be described in relation to the treatment of the venous system of the lower limbs. It is to be understood, however, that the invention is not limited thereto and may be employed intraluminally to treat veins in other areas of the body such as hemorrhoids, esophageal varices, and venous-drainage-impotence of the penis. Furthermore, although the invention will be described as using RF energy from the electrode, it is to be understood that other forms of energy such as microwaves, ultrasound, direct current, circulating heated fluid, radiant light, and lasers can be used, and that the thermal energy generated from a resistive coil or curie point element may be used as well.

Turning to FIG. **3**, one preferred method of the present invention can be performed using the catheter **30** to deliver an expandable electrode device **32** (partially shown) to a venous treatment site in order to ligate the vein. Instead of compressing the tissue surrounding the treatment site via a pressure tourniquet, a tumescent anesthesia technique can be used to inject a dilute anesthetic and vasoconstrictive solution into the tissue surrounding the vein to be treated. The tumescent solution preferably includes mostly saline solution, with a local anesthetic such as Lidocaine, and a vasoconstrictive drug such as Epinephrine. The tumescent solution causes the surrounding tissue **34** to become swollen which compresses the vein **22**, as indicated by the arrows, close to occlusion (in this case) or to occlusion. Sufficient tumescent solution should be delivered into the tissue surrounding the vein to compress and exsanguinate the vein. Before injecting the tumescent solution, the catheter **30** is placed within the vein at the treatment site, with the expandable electrode device retracted.

The solution is typically infused with a peristaltic pump. However, 60 cc or 100 cc syringes **35** can be used. Another alternative is an IV bag with a pressure cuff. Large volumes are typically delivered into the perivenal area via a large cannula. Sites are typically located 10 cm apart down the leg. Usually there are four or five delivery sites. The external result is a leg that appears inflated. The internal result is compressed veins plus an anesthetized leg. The expandable electrode device is then expanded into apposition with the venous tissue after compression of the vein. Energy such as high frequency RF energy is applied from the expandable electrode device to the venous tissue until the vein durably assumes dimensions less than or equal to the compressed dimensions caused by the injection of the tumescent solution into the tissue.

After completing the procedure for a selected venous section or treatment site, the electrode may be retracted and the catheter moved to another venous section where the ligation process is repeated. Ultrasound guidance can be used to monitor the progress of the procedure.

One preferred embodiment of the catheter for delivering an expandable energy application device or expandable electrode device **56** to the venous treatment site is illustrated in FIG. **4**. The catheter **30** includes an expandable energy application device **56** which in this embodiment, comprises an array of electrodes **58**, an outer sheath **36** having a distal orifice **38** at its working end **40**. The connector end **42** of the outer sheath is attached to a handle **44** that includes electrical connector **46**. The handle additionally includes a guide wire port **48**. The connector **46** is for interfacing with a power source, typically an RF generator **50**, and a microprocessor controller **52**. The power source and microprocessor controller are usually contained in one unit. The microprocessor controller controls the RF generator in response to external commands and data from a temperature sensor **54**, such as a thermocouple, or temperature sensors that may be positioned at an intraluminal venous treatment site.

The catheter **30** includes the expandable electrode device **56** that moves in and out of the outer sheath by way of the distal orifice **38** in this embodiment, although in other embodiments the device **56** may expand from and contract into the catheter **30** at other locations. The expandable electrode device **56** includes a plurality of electrodes **58** which can be expanded by moving the outer sheath **36** relative to the electrodes. Although FIG. **4** illustrates a plurality of electrodes **58** surrounding a single central electrode, different electrode configurations may be used.

Contained within the outer sheath **36** is an inner sheath **60** or inner member as shown in the cutaway portion of FIG. **4**. A fluid port **62** communicates with the interior of the outer sheath. The catheter **30** can be periodically flushed out with saline through the fluid port. The flushing fluid can travel between the outer sheath and the inner sheath. The fluid port also allows for the delivery of drug therapies. Flushing out the catheter prevents the buildup of biological fluid, such as

blood, within the catheter. The treatment area or site of the vein can be flushed with a fluid such as saline, or a high impedance dielectric fluid, in order to evacuate blood from the treatment area of the vein so as to prevent the formation of coagulum or thrombosis. The use of a high impedance dielectric fluid can minimize unintended heating effects away from the treatment area. The dielectric fluid directs the current of RF energy toward the vein wall. In addition, a vasoconstrictive agent may be applied to shrink the vein, heparin may be applied for coagulation avoidance, and a sclerosing agent may be applied to assist in ligation. These drugs or agents may be applied before, during, or after the catheter is used to heat the vein wall.

In one preferred embodiment, the catheter **30** includes a lumen which begins at the distal tip **55**, proximate the working end **40**, and runs substantially along the axis of the inner member before terminating at the guide wire port **48** of the handle **44**. A guide wire can be introduced through the lumen of the catheter for use in guiding the catheter to the desired treatment site. Where the catheter is sized to treat smaller veins, the outer diameter of the catheter may not allow for a fluid flush between the outer sheath and the inner sheath **60**. However, a fluid flush can be introduced through the guide wire port **48** in such an embodiment.

Turning again to FIG. **4**, an actuator **76** controls the extension of the electrode device **56** through the distal orifice **38**. The actuator may take the form of a switch, lever **78**, threaded control knob, or other suitable mechanism, and is preferably one that can provide fine control over the movement of the outer sheath **36** or the inner sheath **60**, as the case may be. In one embodiment of the invention, the actuator interfaces with the outer sheath to move it back and forth relative to the inner sheath. In another embodiment the actuator interfaces with the inner sheath to move it back and forth relative to the outer sheath. The relative position between the outer sheath and inner sheath is thus controlled, but other control approaches may be used.

In a preferred embodiment of a catheter **90** is illustrated in FIG. **5**. An inner member **92** or sheath is contained within the outer sheath **94**. The inner sheath is preferably constructed from a flexible polymer such as polymide, polyethylene, or nylon, and can travel the entire length of the catheter. The majority of the catheter should be flexible so as to navigate the tortuous paths of the venous system. A hypotube having a flared distal end **98** and a circular crosssectional shape is attached over the distal end of the inner sheath **92**. The hypotube **96** is preferably no more than about two to three centimeters in length. The hypotube acts as part of a conductive secondary lead **100**. An uninsulated conductive electrode sphere **102** is slipped over the hypotube. The flared distal end of the hypotube prevents the electrode sphere from moving beyond the distal end of the hypotube. The sphere is permanently affixed to the hypotube, such as by soldering the sphere both front and back on the hypotube. The majority of the surface of the electrode sphere remains uninsulated. The remainder of the hypotube is preferably insulated so that the sphere-shaped distal end can act as the electrode. For example, the hypotube can be covered with an insulating material such as a coating of parylene. The interior lumen of the hypotube is lined by the inner sheath **92** which is attached to the flared distal end of the hypotube by adhesive such as epoxy.

Surrounding the secondary lead **100** are a plurality of primary leads **104** that preferably have a flat rectangular strip shape and can act as arms. In one configuration, the strip shape is a width from 0.76 mm (0.03 in) to 1.00 mm (0.04 in) and a thickness of approximately 0.13 mm (0.005 in.). As illustrated in FIG. **6**, the plurality of primary leads **104** is preferably connected to common conductive rings **106**. This configuration maintains the position of the plurality of primary leads, while reducing the number of internal electrical connections. The conductive rings **106** are attached to the inner sheath **92**. The position of the rings and the primary leads relative to the outer sheath **94** follows that of the inner sheath. As earlier described, the hypotube **96** of the secondary lead is also attached to the inner sheath. Two separate conductive rings can be used so that the polarity of different primary leads can be controlled separately. For example, adjacent primary leads can be connected to one of the two separate conductive rings so that the adjacent leads can be switched to have either opposite polarities or the same polarity. The rings are preferably spaced closely together, but remain electrically isolated from each other along the inner sheath. Both the rings and the hypotube are coupled with the inner sheath, and the primary leads that are connected to the rings move together with the secondary lead while remaining electrically isolated from the secondary lead. Epoxy or another suitable adhesive can be used to attach the rings to the inner sheath. The primary leads from the respective rings alternate with each other along the circumference of the inner sheath. The insulation along the underside of the leads prevents an electrical short between the rings. FIG. **6***a* illustrates an end view of the working end of catheter **90** taken along line **6***a*—**6***a* of FIG. **6**.

The conductive rings **106** and the primary leads **104** are attached together to act as cantilevers where the ring forms the base and the rectangular primary leads operate as the cantilever arms. The primary leads are formed to have an arc or bend such that the primary leads act as arms that tend to spring outwardly away from the catheter **90** and toward the surrounding venous tissue. Insulation along the underside of the primary leads and the conductive rings prevents unintended electrical coupling therebetween. Alternately, the primary leads are formed straight and connected to the conductive rings at an angle such that the primary leads tend to expand or spring radially outward from the conductive rings. The angle at which the primary leads are attached to the conductive rings should be sufficient to force the primary distal ends and their electrodes **108** through blood and into apposition with the vein wall **80** but not enough to preclude vein shrinkage. In particular, the primary leads **104** are formed with enough strength, and are mounted or bent such that they expand outwardly into apposition with the inner wall of the vein. However, the force they develop in an outward direction is not strong enough to prevent radial shrinkage of the vein. As the vein shrinks, due to the heating caused by the energy delivered by the electrodes **108**, the shrinking vein causes a contraction of the primary electrodes. Due to the outward force constantly exerted by the primary leads **104**, the electrodes **108** remain in constant apposition with the vein wall as it shrinks.

Other properties of the primary leads, such as lead shape and insulation thickness, affect the push force of the lead against the vein wall and the degree of arc or bend must be adjusted to compensate for these factors. The rectangular cross section of the primary leads can provide increased stability in the lateral direction while allowing the necessary bending in the radial direction. The primary leads are less likely to bend sideways when expanded outward due to the increased size of the rectangular lead in that sideways direction, and a uniform spacing between primary leads is more assured. Uniform spacing between the primary leads and the distal ends promotes uniform heating around the vein by the electrodes **108**.

The distal ends of the primary leads **104** are uninsulated to act as the electrodes **108** having a rounded shape. In the embodiment shown, the shape is convex which may take the form of a spoon or hemispherical shape. The primary leads can be stamped to produce an integral shaped electrode at the distal end of the primary leads. The uninsulated outer portion of the distal end of the electrodes **108** which are to come into apposition with the wall of the vein is preferably rounded and convex. The flattened or non-convex inner portion of the distal end is insulated to minimize any unintended thermal effect, such as on the surrounding blood in a vein. The distal ends of the electrodes **108** are configured such that when the distal ends are forced toward the inner sheath **92**, as shown in FIG. **5***a* the distal ends combine to form a substantially spherical shape with a profile smaller than the spherical electrode **102** at the secondary distal end.

In one preferred embodiment as shown in FIG. **6**, the electrodes **108** comprise a convex, square center section with semi-circular ends. It has been found that this "race track" configuration maximizes surface area of contact for the electrodes **108** shown.

The outer sheath **94** can slide over and surround the primary and secondary leads **100** and **104**. The outer sheath includes an orifice **110** which is dimensioned to have approximately the same size as the spherical electrode **102** at the secondary distal end. A close or snug fit between the spherical electrode **102** and the orifice **110** of the outer sheath is achieved. This configuration provides an atraumatic tip for the catheter **90**. The spherical electrode **102** is preferably slightly larger than the orifice **110**. The inner diameter of the outer sheath is approximately the same as the diameter of the reduced profile of the combined primary distal end electrodes **108**.

A fluid port (not shown) can communicate with the interior of the outer sheath **94** so that fluid can be flushed between the outer sheath and inner sheath **92** as described above. Alternately, a fluid port can communicate with a central lumen **112** in the hypotube which can also accept a guide wire for use in guiding the catheter to the desired treatment site. It is to be understood that another lumen can be formed in the catheter to deliver fluid to the treatment site. The delivered fluid displaces or exsanguinates blood from the vein so as to avoid heating and coagulation of blood. The delivery of a dielectric fluid increases the surrounding impedance so that RF energy is directed into the tissue of the vein wall. An alternate fluid could be a sclerosing agent which could serve to displace blood or to further enhance occlusion of the vein when applied before, during, or after energy delivery. The fluid can also include an anticoagulant such as heparin which can chemically discourage the coagulation of blood at the treatment site. The catheter **90** can be periodically flushed with saline which can prevent the buildup of biological fluid, such as blood, within the catheter. The saline can be flushed through the central lumen **112** or between the inner and outer sheaths. If a central lumen is not desired, the lumen of the hypotube can be filled with solder.

The electrode device **114** can operate in either a bipolar or a monopolar configuration. When adjacent primary leads have opposite polarity, a bipolar electrode operation is available. When the primary leads are commonly charged a monopolar electrode operation is available in combination with a large return electrode pad placed in contact with the patient. When the primary electrodes **108** are commonly charged or have a first potential, and a secondary electrode **102** has an opposite polarity or different potential, a bipolar electrode operation is available. More or fewer leads may be used. The number of leads can be dependent on the size or diameter of the vein to be treated, as described above.

Although not shown, it is to be understood that the catheter **90** can include one or more temperature sensors, such as thermocouples, mounted in place on an electrode **108** so that the sensor is substantially flush with the exposed surface of the electrode **108**. (The sensor is shown in a raised position in the drawings for clarity of illustration only). The temperature sensor senses the temperature of the portion of the vein that is in apposition with the exposed electrode **108** surface. The sensor provides an indication of when shrinkage occurs (70 degrees C. or higher). Application of RF energy from the electrodes **108** is halted or reduced when the monitored temperature reaches or exceeds the specific temperature that was selected by the operator, such as the temperature at which venous tissue begins to cauterize. Other techniques such as impedance monitoring and ultrasonic pulse echoing can be utilized in an automated system which shuts down or regulates the application of RF energy from the electrodes to the venous section when sufficient shrinkage of the vein **22** is detected. This also helps to forestall overheating of the vein.

Referring now to FIGS. **7** and **8**, in the operation of this embodiment of a catheter **90**, the catheter is inserted into a vein **22**. Fluoroscopy, ultrasound, an angioscope imaging technique, or another technique may be used to direct and confirm the specific placement of the catheter in the vein. Impedance measurements can also be used to determine proper positioning of the catheter, particularly at the ostium of a vessel such as at the sapheno-femoral junction. The impedance will be low when the electrodes are in the blood stream. The catheter can then be moved until a high impedance value is obtained, indicating electrode contact with the vein wall. The vein wall **80** has been compressed by the introduction of tumescent anesthesia into the tissue surrounding the vein as indicated by the arrows. The arrows in the figures indicate the compression of the tissue. Unless stated otherwise, all drawing figures having arrows indicating tissue compression are not drawn to scale for purposes of clarity of illustration and are meant to be representations of the vein in a nearly fully occluded state.

The reduction in the vein **22** diameter caused by the tumescence of the issue in contact with the treatment site assists in pre-shaping the vein to be molded to a ligated state. The compression also exsanguinates the vein and forces blood away from the treatment site, thus preventing coagulation.

The actuator **76** (FIG. **4**) is then operated to retract the outer sheath **94** to expose leads the **100** and **104**. As the outer sheath no longer restrains the leads, the primary leads **104** move outward relative to the axis defined by the outer sheath, while the secondary lead **100** remains substantially linear along the axis defined by the outer sheath. The primary leads continue to move outward until their electrodes **108** are placed in apposition with the vein wall **80** and the outward movement of the primary leads is impeded. The primary electrodes **108** contact the vein wall along a generally circumferential area or band of the vein wall. This outward movement of the primary leads occurs in a substantially symmetrical fashion so that the primary electrodes **108** are substantially evenly spaced. Alternately, the electrodes **86** can be spaced apart in a staggered fashion such that they do not lie in the same plane. For example, the adjacent electrodes **86** can extend different lengths from the catheter so that a smaller cross-sectional profile is achieved when the electrodes **86** are collapsed toward one another.

When the electrodes **102** and **108** are positioned at the treatment site of the vein, the RF generator **50** is activated

to provide suitable RF energy. One suitable frequency is 510 kHz. One criterion used in selecting the frequency of the energy to be applied is the control desired over the spread, including the depth, of the thermal effect in the venous tissue. Another criterion is compatibility with filter circuits for eliminating RF noise from thermocouple signals. In a bipolar operation, the primary electrodes **108** are charged with one polarity opposite that of the secondary electrode **102**. The coupling between oppositely charged primary and secondary electrodes produces RF fields therebetween, and form a symmetrical RF field pattern along a circumferential band of the vein wall **80** to achieve a uniform temperature distribution along the vein wall being treated.

The RF energy produces a thermal effect which causes the venous tissue to shrink, reducing the diameter of the vein **22**. The thermal effect produces structural transfiguration of the collagen fibrils in the vein. The collagen fibrils shorten and thicken in cross-section in response to the heat from the thermal effect. As shown in FIG. **8**, the energy causes the vein wall **88** to collapse until further collapse is impeded by the primary lead electrodes **108**. The primary lead electrodes are pressed closer together by the shrinking vein wall and assume a reduced profile shape which is sufficiently small so that the vein is effectively ligated.

The catheter **90** is pulled back while continuing energy delivery as shown in FIG. **9**. Ligation as the catheter is being retracted produces a lengthy occlusion **89** which is stronger and less susceptible to recanalization than an acute point occlusion.

In a monopolar operation, the secondary-lead electrode **102** remains neutral, while the primary electrodes **108** are commonly charged and act in conjunction with an independent electrical device, such as a large low-impedance return pad (not shown) placed in external contact with the body, to form RF fields substantially evenly spaced around the circumference of the vein. The thermal effect produced by those RF fields along the axial length of the vein wall **80** causes the vein wall to collapse around the primary lead electrodes. The electrode device is retracted as described in the bipolar operation.

In either bipolar or monopolar operation the application of RF energy is substantially symmetrically distributed through the vein wall, as previously described. The electrodes should be spaced no more than 4 or 5 millimeters apart along the circumference of the vein wall **80**, which defines the target vein diameter for a designed electrode catheter. Where the electrodes are substantially evenly spaced in a substantially symmetrical arrangement, and the spacing between the electrodes is maintained, a symmetrical distribution of RF energy increases the predictability and uniformity of the shrinkage and the strength of the occlusion.

Although not shown, in another embodiment, the primary leads may be mounted or otherwise configured such that they expand outwardly in an asymmetrical fashion. One purpose for an asymmetrical electrode arrangement is to only shrink a portion of the vein wall to achieve occlusion. Such may be desired in the case of preferentially shrinking a tributary branch or aneurysm on one side of the vein.

After completing the procedure for a selected venous section or treatment site, the actuator **76** causes the primary leads **104** to return to the interior of the outer sheath **94**. Once the primary leads are within the outer sheath, the catheter **90** may be moved to another venous section where the ligation process is repeated.

As illustrated in FIGS. **10** and **11**, another embodiment of an expandable electrode catheter **118** includes two sets of expandable electrode leads **120** and **122**, although additional sets of electrode leads may be possible. The electrodes **124** of this embodiment are similar to the electrodes of the embodiment illustrated in FIG. **6** having electrodes with a rounded, convex, spoon-shaped contact area. Other shapes for the electrode may be used, such as ellipses, rounded, ovals, race tracks, and others. Although only one electrode is indicated by numeral **124** in FIGS. **10** and **11**, this is for purposes of clarity in the drawings only. All electrodes are meant to be indicated by numeral **124**. While each set of electrode leads may include as few as two electrode leads, the illustrated embodiment includes six electrode leads per set, although more than six electrode leads may be used as well.

In the embodiment shown in FIGS. **10** and **11**, the sets of electrode leads **120** and **122** are longitudinally separated from each other. Thus, the electrodes within each set of electrode leads are separated from one another radially and each of those electrodes is also separated from every electrode in the other set longitudinally, due to the longitudinal separation. There therefore exists radial separation and longitudinal separation of electrodes at the working end **126** of the catheter **118** in the arrangement shown in FIGS. **10** and **11**.

With the configuration of electrode leads presented in FIGS. **10** and **11**, greater flexibility exists in establishing current flows through the tissue of a patient. As in previous embodiments, the electrodes expand outwardly into contact with patient tissue. Where all the electrodes of a first set of electrode leads have the same polarity, there may be an odd number of electrodes in the set, or an even number. All electrodes in the set may be connected to a common connection point, such as the conducting ring **106** shown in FIG. **6**. A single conductor from the connecting end of the catheter may power all electrodes of the set by a single connection to that conducting ring. All electrodes of a second set of electrode leads may also be commonly connected at a respective conducting ring but to a different electrical potential than the first set. Because two different electrical potentials exist at the working end of the catheter, energy will flow through the patient tissue between those sets of electrode leads and a bipolar arrangement will exist. Thus, a length of patient tissue, at least as long as the distance between the first and second sets of electrode leads, will receive the energy.

A monopolar arrangement may also be established if desired by setting all electrodes of all electrode leads to the same electrical potential and establishing a different electrical potential outside the patient, such as at a "backplate" in contact with the skin of the patient at a selected location. Energy from the working end **126** of the catheter will then flow through the patient to the return provided by the backplate.

In another arrangement in polarizing or controlling the electrical potential at the electrodes, the electrodes in the first set of electrode leads may be individually controlled so that there are electrode pairs of differing potentials in the set of leads. This would establish a bipolar approach within the first set of leads itself. If the electrodes of the second set of leads are likewise connected for different potentials among themselves, they too would provide a bipolar approach in their own set and currents would flow through patient tissue between the electrodes in each set of leads. If the electrodes having a first polarity in the first set are aligned with the electrodes having a different polarity in the second set of leads, energy would not only flow between the bipolar electrodes within the set but would also flow to the elec-

trodes in the other set resulting in two bipolar arrangements at the single working end of the catheter. Patient tissue of a length at least as great as the distance between the first and second sets of electrode leads will receive energy as well as patient tissue between electrodes within each set of leads itself.

A further arrangement coupled with the bipolar approach just described would be to also use a backplate at a different electrical potential to provide further control over the energy flow through the patient's tissue. In this case, energy would flow between the electrodes within each set of leads, between electrodes in different sets of leads, and between electrodes and the backplate.

In yet a further arrangement, each of the electrodes may be individually connected to a power source (**50**, FIG. **4**) and the electrical potential at each electrode can be individually controlled. This arrangement may yield even more precise control over the current densities through patient tissue. As an example, where less current flow is desired between certain electrodes of a set of leads but more current flow is desired between those electrodes and electrodes of a second set of leads, the potential between the electrodes of the same set may be reduced but the potential between those electrodes and the electrodes of the second set of leads may be increased resulting in the desired current flow densities. In the case where a backplate is also used, the electrodes may be controlled so that energy flows between such electrodes and the backplate. Because each electrode is individually controlled, the level of energy it imparts to the tissue at its location is controllable.

One factor that could affect the number of electrodes per set of electrode leads is the diameter of the vein being treated. The design of the contact pad for the electrode leads could also affect the desired number of electrodes for a given procedure.

In this embodiment, the electrode leads **120**, **122** are formed to expand outwardly into apposition with the target tissue, yet as the target tissue shrinks, the electrodes maintain contact with that tissue and are moved inwardly by that tissue. Because of this arrangement, the leads compensate for variations in the diameter of the vein. They are therefore capable of maintaining apposition with the tissue whether or not compression of the vein or anatomical structure exists, such as by use of a pressure cuff or tourniquet or tumescence of the surrounding tissue.

The tip **128** of the electrode catheter **118** should have a hemispherical or another atraumatic shape. The tip **128** may be electrically neutral, and may be fabricated from a polymer or it may be fabricated of stainless steel. Because the tip **128** has a rounded shape and is located at the distal extreme of the catheter, it may perform a guiding function when introducing the catheter to the patient.

The double set of expandable electrodes can be used to ligate veins or other hollow anatomical structures in a manner similar to that previously described. The outer sheath **130** can be pulled back to allow the electrode to expand outwardly from the catheter and into apposition with the wall of the lumen being treated. The two sets of electrodes **120** and **122** apply energy to the lumen to cause it to shrink to a reduced diameter. The catheter can be moved or pulled back while the energy is being applied to treat an extended area of the lumen. When the desired area of the lumen or vein is treated (e.g., ligated) energy is no longer provided to the electrodes, and the outer sheath **130** is pushed forward to force the expanded electrodes back to an unexpanded condition. The catheter can then be removed from the patient, or another section of the vein can be treated.

The description of the component parts discussed above are for a catheter to be used in a vein ranging in size from 3 mm (0.12 in) to 10 mm (0.39 in) in diameter. It is to be understood that these dimensions do not limit the scope of the invention and are merely exemplary in nature. The dimensions of the component parts may be changed to configure a catheter that may used in various-sized veins or other anatomical structures.

Referring now to FIG. **12**, there is shown a partial cross-section view of the catheter of FIGS. **10** and **11**. Two pluralities of electrodes **120** and **122** are shown with the electrodes of the first plurality **120** being indicated by numeral **124** and the electrodes of the second plurality **122** being indicated by numeral **150**. Each electrode is formed from an electrically-conductive electrode lead **152** and **154** respectively that is electrically insulated along its length except at its distal end at which point no insulation exists thus forming the electrode. Each lead has an outward bend (not shown). An inner tube **156** includes a lumen **158** through which fluid may flow for flush or other purposes, or through which a guide wire may be positioned. A hypotube **160** is positioned over the inner tube and layers of insulation **162** are mounted over the hypotube. The first plurality **120** of electrode leads **152** extend proximally to a first mounting ring **164** to which all are connected. The second plurality **122** of electrode leads **154** extend proximally to a second mounting ring **166** to which all are connected. The rings **164** and **166** are mounted over the hypotube insulation so that no electrical conduction path exists between the two. Wire conductors **168** and **170** extend from the proximal end of the catheter to each ring so that all electrode leads connected to a particular ring are interconnected electrically.

Alternate arrangements are possible and in one, alternating electrodes of a particular plurality are connected to two different rings. Each ring is separately connected to the power source and the polarities of the rings may therefore be made different to establish a bipolar approach within the plurality. One electrode may be a "+" polarity while the two adjacent electrodes may be a "−" polarity. In this case then, there would be a total of three rings for all electrodes. In another arrangement, both pluralities would have two rings for its respective electrodes with alternating electrodes connected to different rings so that bipolar approaches within each plurality may be established. In this case, there would exist a total of four rings for the two pluralities of electrodes.

An outer movable sheath **172** when slid in the distal direction to the point shown in FIG. **12** will cause the electrode leads to contract to the position shown. When slid in the proximal direction a sufficient distance, the sheath **172** acts as a deployment device in that it will move past the bend (not shown) in each of the electrode leads of the second plurality **122** permitting all electrode leads to expand outwardly as shown in FIG. **11**.

The electrode leads are formed of stainless steel in this embodiment and with the thin insulation layer and the outward bend, have enough strength to automatically move outwardly through blood flow (in a venous application) and into apposition with the inner wall of the target tissue. As the inner wall shrinks due to the application of heat by the electrodes, the inner wall will force the electrode leads toward their contracted position but the electrodes will automatically stay in apposition with the inner wall during the entire ligation process due to their outward bends and the material of which they are formed.

In one embodiment shown in FIG. **12**, the electrode **124** includes a temperature sensor **54** and an electrode of the

second plurality also includes a temperature sensor **54**. Although not shown as such, they are mounted flush with the outer electrode surfaces and their wires protrude inwardly through the electrode and are held in place along the respective leads **152** and **154**. In one embodiment, the microprocessor **52** (FIG. **4**) receives the signals from both temperature sensors, averages those signals and determines the effective temperature at the treatment site based on that average signal. Methods of averaging temperature signals are well known to those skilled in the art and no further description is provided here.

Although described above as positively charged, negatively charged, or as a positive conductor or negative conductor, these terms are used for purposes of illustration only. These terms are generally meant to refer to different electrode potentials and are not meant to indicate that any particular voltage is positive or negative. Furthermore, other types of energy such as light energy from fiber optics can be used to create a thermal effect in the hollow anatomical structure undergoing treatment. Additionally, although the electrodes and leads have been described as protruding from a distal orifice in the catheter, they may be expanded by other means and in other configurations. In another embodiments, the leads may be deployed by an inner pull wire, hydraulics, or magnetic fields.

The benefits of tumescence would include locally anesthetizing the treatment area for a prolonged period of time and insulating most of the surrounding tissue and nerves from the damage of heat conducting from the treated vein. An additional benefit of the vasoconstriction induced by the Epinephrine would be that the constricted blood vessels would limit how fast the body absorbed the Lidocaine thus keeping the level of Lidocaine absorbed below the toxicity level. Also, as mentioned supra, extended applications of energy have a greater possibility of increasing the temperature of the blood to an unacceptable level and may result in a significant amount of heat-induced coagulum forming on the electrode and in the vein which is not desirable. Using a tumescent anesthesia compression technique, including the administration of vasocontrictive drugs, would aid in preventing this problem by exsanguinating the vein.

Although described above in terms of a vein, the concepts are generally applicable to other hollow anatomical structures in the body as well. The above description has been generally confined to veins in consideration of avoiding unnecessary repetition.

While several particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A method of applying energy to a hollow anatomical structure from within the hollow portion of the structure, the method comprising the steps of:

introducing a catheter having a working end with an energy application device at the working end into the hollow anatomical structure;

positioning the working end of the catheter proximate a treatment site within the hollow anatomical structure;

injecting a tumescent fluid solution into selected tissue that is in contact with the treatment site to cause the tissue to become tumescent and compress the hollow anatomical structure at the treatment site to a compressed size; and

applying energy to the compressed hollow anatomical structure at the treatment site via the energy application device until the hollow anatomical structure durably assumes a smaller size.

2. The method of claim **1** wherein the step of injecting a tumescent fluid solution comprises the step of injection enough tumescent fluid solution into the tissue such that the tumescent tissue compresses the treatment site sufficiently to exsanguinate blood from the hollow portion of the hollow anatomical structure at the treatment site.

3. The method of claim **1** wherein the step of applying energy comprises the step of applying energy to effectively occlude the treatment site.

4. The method of claim **3** further comprising the step of moving the energy application device along the treatment site while performing the step of applying energy so as to result in a lengthy occlusion of the treatment site.

5. The method of claim **1** wherein the step of applying energy further includes moving the energy application device along the treatment site while performing the step of applying energy.

6. The method of claim **1** wherein the hollow anatomical structure comprises a vein and the treatment site comprises a length of the vein.

7. The method of claim **1** wherein the step of injecting a tumescent fluid solution into selected tissue comprises the step of injecting a tumescent fluid having an anesthetic into the selected tissue.

8. The method of claim **7** wherein the step of injecting a tumescent fluid solution into selected tissue comprises the step of injecting a tumescent fluid having an anesthetic and a vasoconstrictive drug into the selected tissue.

9. The method of claim **1** further comprising the step of delivering fluid from within the hollow structure to the treatment site.

10. The method of claim **9** wherein the step of delivering fluid comprises delivering fluid to exsangulnate the treatment site.

11. The method of claim **9** wherein the step of delivering fluid consists of delivering fluid from the following group:

saline;

vasoconstrictive agent;

sclerosing agent;

high impedance fluid; and

heparin.

12. The method of claim **1** further comprising the steps of:

sensing the temperatures at two separate locations on the energy application device;

averaging the two sensed temperatures at the two separate locations; and

determining a temperature at the energy application device based on the averaged temperatures.

13. The method of claim **1** wherein the step of applying energy to the compressed hollow anatomical structure at the treatment site comprises applying electrical energy to the inner wall of the treatment site with an electrode, the electrode being in apposition with the inner wall.

14. The method of claim **1** wherein the step of applying energy to the compressed hollow anatomical stucture at the treatment site comprises applying electrical energy to the inner wall of the treatment site with an electrode, the electrode being in apposition with the inner wall, the method further comprising the steps of:

applying electrical energy with the electrode to effectively occlude the treatment site at the electrode; and

moving the electrode along the treatment site while maintaining the electrode in apposition with the vein wall

while performing the step of applying energy to effectively occlude the treatment site so as to result in a lengthy effective occlusion of the treatment site.

15. The method of claim **14** wherein the step of applying energy comprises applying sufficient energy to collapse the hollow anatomical structure around the energy application device as it is being moved along the treatment site to result in a lengthy effective occlusion of the treatment site.

16. The method of claim **1** further comprising the step of determining when apposition of the energy application device with the inner wall of the hollow anatomical structure has occurred by monitoring the impedance experienced by the energy application device.

17. The method of claim **14** wherein the step of applying electrical energy to effectively occlude the treatment site at the electrode comprises applying said energy with a plurality of electrodes, and further comprises the steps of:

sensing the temperatures at two separate electrodes; and

averaging the two sensed temperatures; and

determining a temperature at the electrodes based on the averaged temperatures.

18. A method of applying energy to an inner wall of a vein from within the vein along a treatment portion, the method comprising the steps of:

introducing a catheter having a working end with an energy application device at the working end into the treatment portion;

injecting a tumescent fluid solution into selected tissue outside the vein but in contact with the vein at the treatment site to cause the tissue to become tumescent and compress the vein at the treatment site to a compressed size;

applying energy to the compressed vein at the treatment site via the energy application device; and

withdrawing the catheter.

19. The method of claim **18** wherein the step of injecting a tumescent fluid solution comprises the step of injecting enough tumescent fluid solution into the tissue such that the tumescent tissue compresses the treatment site sufficiently to exsanguinate blood from the hollow portion of the hollow anatomical structure at the treatment site.

20. The method of claim **18** further comprising the step of moving the energy application device along the treatment site while performing the step of applying energy so as to result in a lengthy occlusion of the treatment site.

21. The method of claim **18** wherein the step of moving the energy application device comprises moving the energy application device along the treatment site while performing the step of applying energy such that the vein collapses around the energy application device as it is being moved.

22. The method of claim **18** wherein the step of injecting a tumescent fluid solution into selected tissue comprises the step of injecting a tumescent fluid having an anesthetic into the selected tissue.

23. The method of claim **22** wherein the step of injecting a tumescent fluid solution into selected tissue comprises the step of injecting a tumescent fluid having an anesthetic and a vasoconstrictive drug into the selected tissue.

24. The method of claim **18** further comprising the step of delivering fluid to the treatment site.

25. The method of claim **24** wherein the step of delivering fluid comprises delivering fluid to exsanguinate the treatment site.

26. The method of claim **24** wherein the step of delivering fluid consists of delivering fluid from the following group:

saline;

vasoconstrictive agent;

sclerosing agent;

high impedance fluid; and

heparin.

27. The method of claim **18** further comprising the steps of:

sensing the temperatures at two separate locations on the energy application device; and

averaging the two sensed temperatures at the two separate locations;

determining a temperature at the energy application device based on the averaged temperatures.

28. The method of claim **18** wherein the step of applying energy to the compressed vein at the treatment site comprises applying electrical energy to the inner wall of the vein with an electrode, the electrode being in apposition with the inner wall.

29. The method of claim **18** wherein the step of applying energy to the compressed vein at the treatment site comprises applying electrical energy to the inner wall of the treatment site with an electrode, the electrode being in apposition with the inner wall, the method further comprising the steps of:

applying electrical energy with the electrode to effectively occlude the treatment site at the electrode; and

moving the electrode along the treatment site while maintaining the electrode in apposition with the vein wall while performing the step of applying energy to effectively occlude the treatment site so as to result in a lengthy effective occlusion of the treatment site.

30. The method of claim **29** wherein the step of applying energy comprises applying sufficient energy to collapse the vein around the electrode as it is being moved along the treatment site to result in a lengthy effective occlusion of the treatment site.

31. A method of applying energy to a hollow anatomical structure from within the hollow portion of the structure, the hollow anatomical structure having an inner wall, the method comprising the steps of:

introducing a catheter having a working end with an energy application device at the working end into the hollow anatomical structure;

positioning the working end of the catheter proximate a treatment site within the hollow anatomical structure;

determining when apposition of the energy application device with the inner wall of the hollow anatomical structure has occurred by monitoring the impedance experienced by the energy application device; and

applying energy to the hollow anatomical structure at the treatment site via the energy application device until the hollow anatomical structure durably assumes a smaller size.

32. The method of claim **31** wherein the step of applying energy comprises the step of applying energy to effectively occlude the treatment site.

33. The method of claim **31** further comprising the step of moving the energy application device along the treatment site while performing the step of applying energy so as to result in a lengthy occlusion of the treatment site.

34. The method of claim **31** further comprising the step of injecting a tumescent fluid solution into selected tissue surrounding the treatment site to compress the hollow anatomical structure at the treatment site to a compressed size.

35. The method of claim **34** wherein the tumescent fluid solution includes an anesthetic.

36. The method of claim 35 wherein the step of injecting a tumescent fluid solution into selected tissue comprises the step of injecting a tumescent fluid having an anesthetic and a vasoconstrictive drug into the selected tissue.

37. The method of claim 31 further comprising the step of delivering fluid from within the hollow structure to the treatment site.

38. The method of claim 31 further comprising the steps of:

sensing the temperatures at two separate locations on the energy application device;

averaging the two sensed temperatures at the two separate locations; and

determining a temperature at the energy application device based on the averaged temperatures.

39. The method of claim 31 further comprising the steps of:

expanding a plurality of leads outwardly from the working end of the catheter, wherein the distal ends of the leads move away from each other and into non-penetrating contact with the inner wall of the anatomical structure; and

applying energy to the inner wall of the anatomical structure by the distal ends of the leads until the anatomical structure collapses.

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